

US3292103 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:20:34

All time stamps listed in this document are displayed in GMT

US3292103

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 18:45:05

Generated On: 09 Jun 2021 16:20:34

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[Participant ID](#)

US3292103

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

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US3292103

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:45:08

Generated On: 09 Jun 2021 16:20:34

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 08 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | SCRN                                    |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 18:45:07

Generated On: 09 Jun 2021 16:20:34

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



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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 18:45:07

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Date of Informed Consent (dd MMM yyyy) 8 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version Amendment 1 ☒  
Amendment 2 ☐  
Amendment 3 ☐  
Amendment 4 ☐  
Amendment 5 ☐

Was participant enrolled in the study? Yes ☒  
No ☐

If No, indicate reason for screen fail Withdrew Consent ☐  
Inclusion/Exclusion ☐  
Cohort Full ☐  
Other ☐

If reason for screen fail is Other, specify \_\_\_\_\_  
Was this participant screened previously? Yes ☐  
No ☒

If Yes, previous participant number \_\_\_\_\_  
Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 18:45:07

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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) 22 Feb 2021 18:45:08

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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) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| Condition   | ENVIRONMENTAL CEDAR<br>ALLERGY                                   |
| Start date (dd MMM yyyy)                          | UN UNK 1990  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 1990   |
| Start Year (derived)                              | 1990   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 16:13:33

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|   |  |
|---|--|
| Condition   | HARRINGTON ROD IMPLANT   |
| Start date (dd MMM yyyy)                          | UN UNK 1974  |
| 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 1974  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 1974   |
| Start Year (derived)                              | 1974   |
| Stop Month and Year (derived)                     | JAN 1974   |
| Stop Year (derived)                               | 1974   |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 16:13:33

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|   |  |
|---|--|
| Condition   | TOTAL HIP REPLACEMENT  |
| 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 (4)

Data signed: (b) (4) 08 Apr 2021 16:13:33

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|   |  |
|---|--|
| Condition   | C-SECTION  |
| Start date (dd MMM yyyy)                          | UN APR 1984  |
| 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 APR 1984  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | APR 1984   |
| Start Year (derived)                              | 1984   |
| Stop Month and Year (derived)                     | APR 1984   |
| Stop Year (derived)                               | 1984   |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 16:13:33

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|   |  |
|---|--|
| Condition   | C-SECTION  |
| Start date (dd MMM yyyy)                          | UN AUG 1988  |
| 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 AUG 1988  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | AUG 1988   |
| Start Year (derived)                              | 1988   |
| Stop Month and Year (derived)                     | AUG 1988   |
| Stop Year (derived)                               | 1988   |



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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 16:13:33

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|   |  |
|---|--|
| Condition   | BILATERAL DECREASED<br>VISUAL ACUITY                             |
| Start date (dd MMM yyyy)                          | UN UNK 1963  |
| 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 1963   |
| Start Year (derived)                              | 1963   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 16:13:33

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|   |  |
|---|--|
| Condition   | HYPERCHOLERSTEROLEMIA  |
| Start date (dd MMM yyyy)                                | UN UNK 2015  |
| Start date completely unknown                           | False  |
| Condition ongoing at study entry                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ |  |
| Stop date completely unknown                            | False  |
| Start Month and Year (derived)                          | JAN 2015   |
| Start Year (derived)                                    | 2015   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 16:13:33

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Apr 2021 16:13:33

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|   |  |
|---|--|
| Condition   | ESOPHAGEAL REFLUX (GERD)   |
| Start date (dd MMM yyyy)                                | UN UNK 2000  |
| 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 2000   |
| Start Year (derived)                                    | 2000   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| Condition   | HYPOTHYROID  |
| Start date (dd MMM yyyy)                                | UN UNK 2015  |
| Start date completely unknown                           | False  |
| Condition ongoing at study entry                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ |  |
| Stop date completely unknown                            | False  |
| Start Month and Year (derived)                          | JAN 2015   |
| Start Year (derived)                                    | 2015   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 08 Apr 2021 16:13:33

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|   |  |
|---|--|
| Condition   | CHRONIC GENERALIZED JOINT PAIN                                   |
| Start date (dd MMM yyyy)                          | UN UNK 2000  |
| 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 2000   |
| Start Year (derived)                              | 2000   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| Condition   | BILATERAL HIP RHEUMATOID<br>ARTHRITIS                            |
| Start date (dd MMM yyyy)                          | UN UNK 1967  |
| 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 1967   |
| Start Year (derived)                              | 1967   |
| Stop Month and Year (derived)                     | JAN 1999   |
| Stop Year (derived)                               | 1999   |

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| Condition   | SCOLIOSIS  |
| Start date (dd MMM yyyy)                          | UN UNK 1974  |
| 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 1974  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 1974   |
| Start Year (derived)                              | 1974   |
| Stop Month and Year (derived)                     | JAN 1974   |
| Stop Year (derived)                               | 1974   |



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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| Condition   | LOW PROGESTERONE   |
| Start date (dd MMM yyyy)                          | UN UNK 2015  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2015   |
| Start Year (derived)                              | 2015   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| Condition   | POST MENOPAUSAL  |
| Start date (dd MMM yyyy)                                | UN UNK 2007  |
| 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 2007   |
| Start Year (derived)                                    | 2007   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 18:45:08

Generated On: 09 Jun 2021 16:20:34

|                                     |                                      |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/> |
|                                     | No <input type="radio"/>             |
| Date of assessment (dd MMM yyyy)    | 08 AUG 2020                          |
| Time of assessment (00:00-23:59)    | 16:05 (24 HR)                        |
| Vital Signs Date and Time (derived) | 08 AUG 2020 16:05                    |
| Height (xxx.x)                      | 159.3 cm                             |
| Weight (xxx.x)                      | 62.9 kg                              |
| BMI (xxx.x)                         | 24.78672 kg/m <sup>2</sup>           |
| BMI units                           | KG/M2                                |
| Temperature (xxx.x)                 | ND - Not Done                        |
| Route of measurement                | Oral <input type="radio"/>           |
|                                     | Axillary <input type="radio"/>       |
|                                     | Other <input type="radio"/>          |
| If Other, specify                   |                                      |
| Pulse (xxx)                         | ND - Not Done                        |
| Pulse units                         | BPM                                  |
| Respiratory Rate (xxx)              | ND - Not Done                        |
| Respiratory Rate units              | BREATHS/MIN                          |
| Systolic Blood Pressure (xxx)       | ND - Not Done                        |
| Systolic Blood Pressure units       | MMHG                                 |
| Diastolic Blood Pressure (xxx)      | ND - Not Done                        |
| Diastolic Blood Pressure units      | MMHG                                 |
| Height (derived)                    |                                      |
| Weight (derived)                    |                                      |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:45:08

Generated On: 09 Jun 2021 16:20:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Feb 2021 18:45:07

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Date of assessment (dd MMM yyyy) 08 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2007

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 18:45:08

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 18:45:08

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:45:08

Generated On: 09 Jun 2021 16:20:34

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 08 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT1                                  |



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 18:45:08

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What was the date of randomization? (dd MMM yyyy) 08 AUG 2020

What was the participant's randomization number? 185367

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 18:45:08

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 18:45:08

Generated On: 09 Jun 2021 16:20:34

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| Timepoint                           | Pre-Dose <input checked="" type="radio"/><br>Post-Dose <input type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 08 AUG 2020  |
| Time of assessment (00:00-23:59)    | 16:05 (24 HR)  |
| Vital Signs Date and Time (derived) | 08 AUG 2020 16:05  |
| Temperature (xxx.x)                 | 037.0 C  |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 078 beats/min  |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 012 breaths/min  |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 159 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 081 mmHg   |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 18:45:08

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|                                     |   |
|-------------------------------------|---|
| Height                              | ND - Not Done   |
| Weight                              | ND - Not Done   |
| Timepoint                           | Pre-Dose <input type="checkbox"/><br>Post-Dose <input checked="" type="checkbox"/>                              |
| Were vital signs assessed?          | Yes <input checked="" type="checkbox"/><br>No <input type="checkbox"/>  |
| Date of assessment (dd MMM yyyy)    | 08 AUG 2020   |
| Time of assessment (00:00-23:59)    | 18:55 (24 HR)   |
| Vital Signs Date and Time (derived) | 08 AUG 2020 18:55   |
| Temperature (xxx.x)                 | 037.1 C   |
| Route of measurement                | Oral <input checked="" type="checkbox"/><br>Axillary <input type="checkbox"/><br>Other <input type="checkbox"/> |
| If Other, specify                   |   |
| Pulse (xxx)                         | 084 beats/min   |
| Pulse units                         | BPM   |
| Respiratory Rate (xxx)              | 014 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN   |
| Systolic Blood Pressure (xxx)       | 157 mmHg  |
| Systolic Blood Pressure units       | MMHG  |
| Diastolic Blood Pressure (xxx)      | 084 mmHg  |
| Diastolic Blood Pressure units      | MMHG  |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:45:08

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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: Exposure

Data signed: (b) (4) 22 Feb 2021 18:45:08

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Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 8 AUG 2020

What was the treatment time? (00:00-23:59) 18:22 (24 HR)

Treatment Date and Time (derived) 8 AUG 2020 18:22

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

US3292103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:45:08

Generated On: 09 Jun 2021 16:20:34

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 08 AUG 2020                          |
| Collection time (00:00-23:59)      | 16:30 (24 HR)                        |
| Collection date and time (derived) | 08 AUG 2020 16:30                    |

US3292103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 18:45:08

Generated On: 09 Jun 2021 16:20:34

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 08 AUG 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 16:25                           | 08 AUG 2020 16:25                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |



US3292103

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:45:08

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

08 AUG 2020 18:55

PC Open Date & Time

08 AUG 2020 18:42

PC Close Date & Time

08 AUG 2020 21:12

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 08 AUG 2020 22:08

PC Open Date & Time 08 AUG 2020 22:07

PC Close Date & Time 09 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

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

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 09 AUG 2020 18:01 |
| PC Open Date & Time  | 09 AUG 2020 12:00 |
| PC Close Date & Time | 10 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

|  |                                      |
|--|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 98.0 °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        | 10 AUG 2020 18:28 |
| PC Open Date & Time  | 10 AUG 2020 12:00 |
| PC Close Date & Time | 11 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

|  |                                      |
|--|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 97.8 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input 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        | 11 AUG 2020 16:57 |
| PC Open Date & Time  | 11 AUG 2020 12:00 |
| PC Close Date & Time | 12 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

|  |                                      |
|--|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 98.2 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input 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        | 12 AUG 2020 17:33 |
| PC Open Date & Time  | 12 AUG 2020 12:00 |
| PC Close Date & Time | 13 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 13 AUG 2020 17:24

PC Open Date & Time 13 AUG 2020 12:00

PC Close Date & Time 14 AUG 2020 11:59



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

|  |                                      |
|--|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 98.0 °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        | 14 AUG 2020 16:51 |
| PC Open Date & Time  | 14 AUG 2020 12:00 |
| PC Close Date & Time | 15 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:20:34

**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

97.8 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

15 AUG 2020 15:58

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:20:34

**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.

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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              | 96.8 °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        | 16 AUG 2020 15:16 |
| PC Open Date & Time  | 16 AUG 2020 12:00 |
| PC Close Date & Time | 17 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:20:34

**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.

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

|  |                                      |
|--|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 97.7 °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        | 17 AUG 2020 14:18 |
| PC Open Date & Time  | 17 AUG 2020 12:00 |
| PC Close Date & Time | 18 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 11

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

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

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

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

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

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

|  |                                      |
|--|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 98.2 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input 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        | 18 AUG 2020 16:07 |
| PC Open Date & Time  | 18 AUG 2020 12:00 |
| PC Close Date & Time | 19 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 12

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 19 AUG 2020 18:17

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 13

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              | 98.0 °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        | 20 AUG 2020 15:24 |
| PC Open Date & Time  | 20 AUG 2020 12:00 |
| PC Close Date & Time | 21 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 14

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

21 AUG 2020 23:59

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 15

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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 22 AUG 2020 17:12

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 16

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

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

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

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

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

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

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

|  |                                      |
|--|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 97.5 °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        | 23 AUG 2020 16:07 |
| PC Open Date & Time  | 23 AUG 2020 12:00 |
| PC Close Date & Time | 24 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 17

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 14:54

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**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

08 AUG 2020 18:55

PC Open Date & Time

08 AUG 2020 18:42

PC Close Date & Time

08 AUG 2020 21:12

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 22:09

PC Open Date & Time

08 AUG 2020 22:07

PC Close Date & Time

09 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 18:02

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 18:29

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 16:58

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 17:34

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 17:24

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 16:51

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 08 AUG 2020 18:56 |
| PC Open Date & Time  | 08 AUG 2020 18:42 |
| PC Close Date & Time | 08 AUG 2020 21:12 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 08 AUG 2020 22:10 |
| PC Open Date & Time  | 08 AUG 2020 22:07 |
| PC Close Date & Time | 09 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 09 AUG 2020 18:03 |
| PC Open Date & Time          | 09 AUG 2020 12:00 |
| PC Close Date & Time         | 10 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 10 AUG 2020 18:30 |
| PC Open Date & Time          | 10 AUG 2020 12:00 |
| PC Close Date & Time         | 11 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 11 AUG 2020 16:58 |
| PC Open Date & Time          | 11 AUG 2020 12:00 |
| PC Close Date & Time         | 12 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 12 AUG 2020 17:35 |
| PC Open Date & Time          | 12 AUG 2020 12:00 |
| PC Close Date & Time         | 13 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 13 AUG 2020 17:25 |
| PC Open Date & Time          | 13 AUG 2020 12:00 |
| PC Close Date & Time         | 14 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 14 AUG 2020 16:52 |
| PC Open Date & Time          | 14 AUG 2020 12:00 |
| PC Close Date & Time         | 15 AUG 2020 11:59 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 8  |
| 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   | 15 AUG 2020 15:58  |
| PC Open Date & Time   | 15 AUG 2020 12:00  |
| PC Close Date & Time  | 16 AUG 2020 11:59  |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <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 checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 16 AUG 2020 15:16  |
| PC Open Date & Time   | 16 AUG 2020 12:00  |
| PC Close Date & Time  | 17 AUG 2020 11:59  |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <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   | 17 AUG 2020 14:18  |
| PC Open Date & Time   | 17 AUG 2020 12:00  |
| PC Close Date & Time  | 18 AUG 2020 11:59  |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 11   |
| 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   | 18 AUG 2020 16:07  |
| PC Open Date & Time   | 18 AUG 2020 12:00  |
| PC Close Date & Time  | 19 AUG 2020 11:59  |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 12   |
| 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   | 19 AUG 2020 18:17  |
| PC Open Date & Time   | 19 AUG 2020 12:00  |
| PC Close Date & Time  | 20 AUG 2020 11:59  |



US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 13   |
| 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   | 20 AUG 2020 15:24  |
| PC Open Date & Time   | 20 AUG 2020 12:00  |
| PC Close Date & Time  | 21 AUG 2020 11:59  |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 14   |
| 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   | 21 AUG 2020 23:59  |
| PC Open Date & Time   | 21 AUG 2020 12:00  |
| PC Close Date & Time  | 22 AUG 2020 11:59  |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 15   |
| 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   | 22 AUG 2020 17:12  |
| PC Open Date & Time   | 22 AUG 2020 12:00  |
| PC Close Date & Time  | 23 AUG 2020 11:59  |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 16   |
| 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   | 23 AUG 2020 16:07  |
| PC Open Date & Time   | 23 AUG 2020 12:00  |
| PC Close Date & Time  | 24 AUG 2020 11:59  |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 17   |
| 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   | 24 AUG 2020 14:54  |
| PC Open Date & Time   | 24 AUG 2020 12:00  |
| PC Close Date & Time  | 25 AUG 2020 11:59  |

US3292103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3292103

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:45:09

Generated On: 09 Jun 2021 16:20:34

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 5 SEP 2020                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT2                                  |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 18:45:09

Generated On: 09 Jun 2021 16:20:34

|                                     |   |
|-------------------------------------|---|
| Timepoint                           | Pre-Dose <input checked="" type="radio"/> |
|                                     | Post-Dose <input type="radio"/>           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of assessment (dd MMM yyyy)    | 5 SEP 2020                                |
| Time of assessment (00:00-23:59)    | 12:33 (24 HR)                             |
| Vital Signs Date and Time (derived) | 5 SEP 2020 12:33                          |
| Temperature (xxx.x)                 | 36.4 C                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 79 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 16 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 137 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 74 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 18:45:09

Generated On: 09 Jun 2021 16:20:34

|                                     |   |
|-------------------------------------|---|
| Timepoint                           | Pre-Dose <input type="checkbox"/>             |
|                                     | Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed?          | Yes <input checked="" type="checkbox"/>       |
|                                     | No <input type="checkbox"/>                   |
| Date of assessment (dd MMM yyyy)    | 5 SEP 2020                                    |
| Time of assessment (00:00-23:59)    | 13:51 (24 HR)                                 |
| Vital Signs Date and Time (derived) | 5 SEP 2020 13:51                              |
| Temperature (xxx.x)                 | 36.7 C  |
| Route of measurement                | Oral <input checked="" type="checkbox"/>      |
|                                     | Axillary <input type="checkbox"/>             |
|                                     | Other <input type="checkbox"/>                |
| If Other, specify                   |   |
| Pulse (xxx)                         | 75 beats/min                                  |
| Pulse units                         | BPM   |
| Respiratory Rate (xxx)              | 16 breaths/min                                |
| Respiratory Rate units              | BREATHS/MIN                                   |
| Systolic Blood Pressure (xxx)       | 127 mmHg                                      |
| Systolic Blood Pressure units       | MMHG  |
| Diastolic Blood Pressure (xxx)      | 76 mmHg                                       |
| Diastolic Blood Pressure units      | MMHG  |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:45:09

Generated On: 09 Jun 2021 16:20:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 SEP 2020

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

US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 18:45:09

Generated On: 09 Jun 2021 16:20:34

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 5 SEP 2020

What was the treatment time? (00:00-23:59) 13:21 (24 HR)

Treatment Date and Time (derived) 5 SEP 2020 13:21

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



US3292103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:45:09

Generated On: 09 Jun 2021 16:20:34

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 5 SEP 2020                           |
| Collection time (00:00-23:59)      | 12:42 (24 HR)                        |
| Collection date and time (derived) | 5 SEP 2020 12:42                     |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 18:45:08

Generated On: 09 Jun 2021 16:20:34

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 5 SEP 2020                         |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 12:48                           | 5 SEP 2020 12:48                   |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:45:09

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

05 SEP 2020 13:54

PC Open Date & Time

05 SEP 2020 13:41

PC Close Date & Time

05 SEP 2020 16:11

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐  
No ☒

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 05 SEP 2020 19:33 |
| PC Open Date & Time  | 05 SEP 2020 17:06 |
| PC Close Date & Time | 06 SEP 2020 11:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 18:31

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

07 SEP 2020 17:03

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 19:14

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59



US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

09 SEP 2020 17:14

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

10 SEP 2020 18:33

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

11 SEP 2020 17:32

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**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

05 SEP 2020 13:54

PC Open Date & Time

05 SEP 2020 13:41

PC Close Date & Time

05 SEP 2020 16:11

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 19:34

PC Open Date & Time

05 SEP 2020 17:06

PC Close Date & Time

06 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 18:32

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 17:04

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 19:14

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59



US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 17:15

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 18:34

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 17:32

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 05 SEP 2020 13:55 |
| PC Open Date & Time  | 05 SEP 2020 13:41 |
| PC Close Date & Time | 05 SEP 2020 16:11 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 05 SEP 2020 19:34 |
| PC Open Date & Time  | 05 SEP 2020 17:06 |
| PC Close Date & Time | 06 SEP 2020 11:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 SEP 2020 18:32 |
| PC Open Date & Time          | 06 SEP 2020 12:00 |
| PC Close Date & Time         | 07 SEP 2020 11:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 07 SEP 2020 17:04 |
| PC Open Date & Time          | 07 SEP 2020 12:00 |
| PC Close Date & Time         | 08 SEP 2020 11:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 08 SEP 2020 19:14 |
| PC Open Date & Time          | 08 SEP 2020 12:00 |
| PC Close Date & Time         | 09 SEP 2020 11:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 09 SEP 2020 17:15 |
| PC Open Date & Time          | 09 SEP 2020 12:00 |
| PC Close Date & Time         | 10 SEP 2020 11:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 10 SEP 2020 18:34 |
| PC Open Date & Time          | 10 SEP 2020 12:00 |
| PC Close Date & Time         | 11 SEP 2020 11:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 11 SEP 2020 17:33 |
| PC Open Date & Time          | 11 SEP 2020 12:00 |
| PC Close Date & Time         | 12 SEP 2020 11:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 8

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 ☐

PC Time Stamp 12 SEP 2020 12:21

PC Open Date & Time 12 SEP 2020 12:00

PC Close Date & Time 13 SEP 2020 11:59

US3292103

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 8  |
| 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   | 12 SEP 2020 12:21  |
| PC Open Date & Time   | 12 SEP 2020 12:00  |
| PC Close Date & Time  | 13 SEP 2020 11:59  |

US3292103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3292103

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:45:09

Generated On: 09 Jun 2021 16:20:34

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 6 OCT 2020                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT3                                  |

US3292103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 18:45:09

Generated On: 09 Jun 2021 16:20:34

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 6 OCT 2020                            |
| Time of assessment (00:00-23:59)    | 10:27 (24 HR)                         |
| Vital Signs Date and Time (derived) | 6 OCT 2020 10:27                      |
| Temperature (xxx.x)                 | 36.3 C                                |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 70 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 12 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 132 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 77 mmHg                               |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |

US3292103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 18:45:09

Generated On: 09 Jun 2021 16:20:34

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3292103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 18:45:09

Generated On: 09 Jun 2021 16:20:34

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 6 OCT 2020                           |
| Collection time (00:00-23:59)      | 10:40 (24 HR)                        |
| Collection date and time (derived) | 6 OCT 2020 10:40                     |

US3292103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:45:09

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 64   |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 08 OCT 2020 11:49:07   |
| Patient Cloud Open Date & Time  | 08 OCT 2020 00:01  |
| Patient Cloud Close Date & Time   | 12 OCT 2020 23:59  |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 71

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

No ☒

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 OCT 2020 14:00:21

Patient Cloud Open Date & Time

15 OCT 2020 00:01

Patient Cloud Close Date & Time

19 OCT 2020 23:59

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 78   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 22 OCT 2020 13:37:05   |
| Patient Cloud Open Date & Time  | 22 OCT 2020 00:01  |
| Patient Cloud Close Date & Time   | 26 OCT 2020 23:59  |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 92   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 06 NOV 2020 12:12:36   |
| Patient Cloud Open Date & Time  | 05 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 09 NOV 2020 23:59  |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 99   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 12 NOV 2020 17:40:52   |
| Patient Cloud Open Date & Time  | 12 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 16 NOV 2020 23:59  |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 106   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq$ 100.4°F/38°C)   | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 103  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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   | 19 NOV 2020 17:36:24   |
| Patient Cloud Open Date & Time  | 16 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 20 NOV 2020 23:59  |



US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 110  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 23 NOV 2020 10:32:55   |
| Patient Cloud Open Date & Time  | 23 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 27 NOV 2020 23:59  |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 14:26:46

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 124

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

No ☒

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 DEC 2020 17:43:06

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 21:41:35

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 138

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

No ☒

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 09:40:09

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 10:34:09

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 09:42:34

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 10:18:09

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59



US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 166  |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 20 JAN 2021 12:25:07   |
| Patient Cloud Open Date & Time  | 18 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 22 JAN 2021 23:59  |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 173  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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   | 27 JAN 2021 10:04:56   |
| Patient Cloud Open Date & Time  | 25 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 29 JAN 2021 23:59  |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 09:50:01

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 187  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 10 FEB 2021 12:00:30   |
| Patient Cloud Open Date & Time  | 08 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 12 FEB 2021 23:59  |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 194  |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 18 FEB 2021 18:06:30   |
| Patient Cloud Open Date & Time  | 15 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 19 FEB 2021 23:59  |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 201

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

No ☒

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

24 FEB 2021 17:18:15

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 12:03:00

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 12:16:57

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59



US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 12:14:04

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 14:03:16

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 236  |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><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   | 31 MAR 2021 12:01:07   |
| Patient Cloud Open Date & Time  | 29 MAR 2021 00:01  |
| Patient Cloud Close Date & Time   | 02 APR 2021 23:59  |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 08:41:55

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 08:18:07

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 10:36:51

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 12:16:37

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAY 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 278   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAY 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 292   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2021 00:01

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04 JUN 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 306

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

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11 JUN 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 313   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUN 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

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25 JUN 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 327

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



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUL 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 334   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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05 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUL 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 341   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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12 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUL 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 348   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 355   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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02 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 AUG 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 369   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 AUG 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 376   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 AUG 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 383   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 390   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 397   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 404   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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



**US3292103**

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**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 418   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 OCT 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 432   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 439   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 OCT 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

29 OCT 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 453   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 NOV 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 467   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 15 NOV 2021 00:01 |
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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 NOV 2021 23:59 |
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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 474   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 NOV 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 488

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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 ☐

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 DEC 2021 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 516   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 17 JAN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 21 JAN 2022 23:59 |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 537   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 544

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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[Patient Cloud Open Date & Time](#)

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31 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 FEB 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 551   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 FEB 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 579   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |



**US3292103**

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**Form: Safety Follow Up Diary**

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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 ☐

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07 MAR 2022 00:01

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11 MAR 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 586   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 MAR 2022 00:01

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18 MAR 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 593   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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21 MAR 2022 00:01

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25 MAR 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

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

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|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | 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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28 MAR 2022 00:01

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01 APR 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 607   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |



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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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04 APR 2022 00:01

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08 APR 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

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

**Form: Safety Follow Up Diary**

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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18 APR 2022 00:01

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22 APR 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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25 APR 2022 00:01

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29 APR 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 635   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |



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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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02 MAY 2022 00:01

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06 MAY 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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**Form: Safety Follow Up Diary**

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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 ☐

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13 MAY 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 23 MAY 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 27 MAY 2022 23:59 |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 670   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUN 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 677   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 13 JUN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 17 JUN 2022 23:59 |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 684   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 691   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 698   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUL 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 705   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 712   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 25 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 JUL 2022 23:59 |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 726   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 733   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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08 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 15 AUG 2022 00:01 |
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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 AUG 2022 23:59 |
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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 747   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 754   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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05 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 SEP 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 768   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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12 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 SEP 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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 ☐



**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 782   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

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26 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 SEP 2022 23:59

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US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

| TIMEPOINT   | DAY 789   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 10 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 OCT 2022 23:59 |

US3292103

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:20:34

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No  |  | 28 FEB 2021 10:45:02      |



US3292103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:45:07

Generated On: 09 Jun 2021 16:20:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:45:07

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 1 MAR 2021                              |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT4                                  |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

Were vital signs assessed? Yes ☐  
No ☒

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

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3292103

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3292103

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 1 MAR 2021                           |
| Collection time (00:00-23:59)      | 11:59 (24 HR)                        |
| Collection date and time (derived) | 1 MAR 2021 11:59                     |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292103

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292103

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3292103**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



**US3292103**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292103

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:20:34

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

**US3292103**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 16:20:34**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3292103

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

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

US3292103

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

Date of updated informed consent (dd MMM yyyy) 12 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 12 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3292103

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

|                                    |                                      |
|------------------------------------|--------------------------------------|
| 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)      | 14:19 (24 HR)                        |
| Collection date and time (derived) | 12 JAN 2021 14:19                    |

US3292103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

|                                    |                                      |
|------------------------------------|--------------------------------------|
| 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)    | 14:35                                |
| Collection Date and Time (derived) | 12 JAN 2021 14:35                    |

US3292103

Folder: Unscheduled 08 Aug 2020

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

|            |             |
|------------|-------------|
| Visit Date | 08 AUG 2020 |
|------------|-------------|

Please check all assessments that apply for this visit

|               |       |
|---------------|-------|
| Physical Exam | False |
|---------------|-------|

|             |      |
|-------------|------|
| Vital Signs | True |
|-------------|------|

|                           |       |
|---------------------------|-------|
| Immunogenicity Assessment | False |
|---------------------------|-------|

|                |       |
|----------------|-------|
| Pregnancy Test | False |
|----------------|-------|



US3292103

Folder: Unscheduled 08 Aug 2020

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

|                                     |                                      |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/> |
|                                     | No <input type="radio"/>             |
| Date of assessment (dd MMM yyyy)    | 08 AUG 2020                          |
| Time of assessment (00:00-23:59)    | 16:10 (24 HR)                        |
| Vital Signs Date and Time (derived) | 08 AUG 2020 16:10                    |
| Temperature (xxx.x)                 | ND - Not Done                        |
| Route of measurement                | Oral <input type="radio"/>           |
|                                     | Axillary <input type="radio"/>       |
|                                     | Other <input type="radio"/>          |
| If Other, specify                   |                                      |
| Pulse (xxx)                         | ND - Not Done                        |
| Pulse units                         | BPM                                  |
| Respiratory Rate (xxx)              | ND - Not Done                        |
| Respiratory Rate units              | BREATHS/MIN                          |
| Systolic Blood Pressure (xxx)       | 161 mmHg                             |
| Systolic Blood Pressure units       | MMHG                                 |
| Diastolic Blood Pressure (xxx)      | 86 mmHg                              |
| Diastolic Blood Pressure units      | MMHG                                 |
| Height (derived)                    |                                      |
| Weight (derived)                    |                                      |

US3292103

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 18:45:05

Generated On: 09 Jun 2021 16:20:34

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 14:02:03

Generated On: 09 Jun 2021 16:20:34

|  |  |
|--|--|
| AEID   | USA-US072-2020-MRNA-1273-P30<br>1000013  |
| Adverse event  | SUBDURAL HEMATOMA  |
| 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)                                       | 14 NOV 2020  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         | 26 JAN 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 | True   |
| Hospital Admission Date (dd MMM yyyy)                          | 15 NOV 2020  |
| Hospital Discharge Date (dd MMM yyyy)                          | 17 NOV 2020  |
| Admitted to ICU?   | Yes <input checked="" type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>  |

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US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 14:02:03

Generated On: 09 Jun 2021 16:20:34

|  |   |
|--|---|
| Number of Days in ICU  | 3   |
| 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 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   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | True  |
| 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  |   |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 14:02:03

Generated On: 09 Jun 2021 16:20:34

---

PATIENT CALLED STAFF ON  
20NOV2020 TO REPORT THAT  
SHE HAD BEEN HOSPITALIZED  
FOR THREE DAYS DUE TO A  
SUBDURAL HEMATOMA  
SUFFERED AFTER A FALL.  
PATIENT DOES HAVE A  
MEDICAL HISTORY OF ROD  
IMPLANT DUE TO SCOLIOSIS  
AND A TOTAL HIP  
REPLACEMENT DUE TO  
RHEUMATOID ARTHRITIS,  
WHICH SHE CLAIMS,  
CONTRIBUTED TO HER FALL.  
PATIENT STATES SHE WAS  
TESTED FOR COVID-19 AND  
TESTS CAME BACK NEGATIVE.  
INTAKE AND DISCHARGE CT  
SCANS COMPLETED AND  
KEPPRA WAS PRESCRIBED  
WHILE INPATIENT TO PREVENT  
SEIZURES. MEDICAL RECORDS  
WILL BE REQUESTED ASAP.

---

|  |   |
|--|---|
| 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)       | 1 |

---

US3292103

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 14:02:03

Generated On: 09 Jun 2021 16:20:34

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | FALL   |
| 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)                                       | 14 NOV 2020  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         | 14 NOV 2020  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | False  |
| Hospital Admission Date (dd MMM yyyy)                          |  |
| Hospital Discharge Date (dd MMM yyyy)                          |  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>   |
| Number of Days in ICU  |  |

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Folder: Adverse Events

Form: Adverse Events (2)

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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  | 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:<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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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 ☐

---

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)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED JOINT PAIN

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
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 2000              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____             |                          |                                  |
| Interval Dosage Unit Number (derived) _____        |                          |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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Name of Medication MAGNESIUM CITRATE

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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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 2014              |                                  |
| 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)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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Name of Medication ALLEGRA

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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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) _____             |                          |                                  |
| Interval Dosage Unit Number (derived) _____        |                          |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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Name of Medication FISH OIL

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

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)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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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 2015              |                                  |
| 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) 16 Apr 2021 14:02:03

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Name of Medication CENTRUM SILVER

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

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 (5)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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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 2015              |                                  |
| 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) 16 Apr 2021 14:02:03

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Name of Medication VITAMIN K

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

Dose per administration 100

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 (6)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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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 2015              |                                  |
| 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) 16 Apr 2021 14:02:03

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Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

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)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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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 2015              |                                  |
| 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) 16 Apr 2021 14:02:03

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Name of Medication CALCIUM

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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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 2015              |                                  |
| 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 (9)

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Name of Medication VITAMIN B

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

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)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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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 2015              |                                  |
| 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) 16 Apr 2021 14:02:03

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Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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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 2005              |                                  |
| 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 AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 (11)

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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 2005              |                                  |
| 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 (12)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Form: Prior/Concomitant Medication and Vaccination (12)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           | UN UNK 2015              |                                  |
| 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 (13)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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Name of Medication LOSTARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100

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 (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)                           | UN UNK 2005              |                                  |
| 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 (14)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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Name of Medication ARMOUR THYROID

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROID

Dose per administration 60

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 (14)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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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 2015              |                                  |
| 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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Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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Name of Medication PROGESTERONE

Prophylaxis Yes ☐  
No ☒

Indication LOW PROGESTERONE

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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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 2015              |                                  |
| 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 (16)

Data signed: (b) (4) 16 Apr 2021 14:02:03

Generated On: 09 Jun 2021 16:20:34

Name of Medication NEXIUM

Prophylaxis Yes ☐  
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 14:02:03

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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 2000                          |                          |
| 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 (18)

Data signed: (b) (4) 16 Apr 2021 14:02:03

Generated On: 09 Jun 2021 16:20:34

Name of Medication KEPPRA

Prophylaxis Yes ☒  
No ☐

Indication SEIZURE PREVENTION  
FOLLOWING SUBDURAL  
HEMATOMA

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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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)                       | 14 NOV 2020              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 22 NOV 2020              |                                     |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               | 2                        |                                     |
| Interval Dosage Unit Number (derived)          | 1                        |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 14:02:03

Generated On: 09 Jun 2021 16:20:34

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR FLU  
PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 14:02:03

Generated On: 09 Jun 2021 16:20:34

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="radio"/>            |
|  | Intramuscular            | <input checked="" type="radio"/> |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input type="radio"/>            |
|  | Vaginal                  | <input type="radio"/>            |
|  | Rectal                   | <input type="radio"/>            |
|  | Intravenous              | <input type="radio"/>            |
|  | Intravenous Bolus        | <input type="radio"/>            |
|  | Intravenous Drip         | <input type="radio"/>            |
|  | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 06 OCT 2020                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?   | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 06 OCT 2020                      |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____             |                          |                                  |
| Interval Dosage Unit Number (derived) _____        |                          |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 14:02:03

Generated On: 09 Jun 2021 16:20:34

Name of Medication PNEUMOVAX

Prophylaxis Yes ☒  
No ☐

Indication VACCINE FOR PNEUMONIA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 14:02:03

Generated On: 09 Jun 2021 16:20:34

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input checked="" type="radio"/> |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input type="radio"/>            |
|  | Vaginal                  | <input type="radio"/>            |
|  | Rectal                   | <input type="radio"/>            |
|  | Intravenous              | <input type="radio"/>            |
|  | Intravenous Bolus        | <input type="radio"/>            |
|  | Intravenous Drip         | <input type="radio"/>            |
|  | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 16 DEC 2020                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?   | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 16 DEC 2020                      |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____             |                          |                                  |
| Interval Dosage Unit Number (derived) _____        |                          |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 14:02:03

Generated On: 09 Jun 2021 16:20:34

Name of Medication TETANUS SHOT

Prophylaxis Yes ☒  
No ☐

Indication VACCINE FOR TETANUS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 14:02:03

Generated On: 09 Jun 2021 16:20:34

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input checked="" type="radio"/> |
|  | Respiratory (Inhalation) | <input type="radio"/>            |
|  | Intralesional            | <input type="radio"/>            |
|  | Intraperitoneal          | <input type="radio"/>            |
|  | Nasal                    | <input type="radio"/>            |
|  | Vaginal                  | <input type="radio"/>            |
|  | Rectal                   | <input type="radio"/>            |
|  | Intravenous              | <input type="radio"/>            |
|  | Intravenous Bolus        | <input type="radio"/>            |
|  | Intravenous Drip         | <input type="radio"/>            |
|  | Other                    | <input type="radio"/>            |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 15 NOV 2020                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?   | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 15 NOV 2020                      |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____             |                          |                                  |
| Interval Dosage Unit Number (derived) _____        |                          |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |



US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 16:13:33

Generated On: 09 Jun 2021 16:20:34

| Procedure/Surgery date (dd MMM<br>yyyy) | Procedure/Surgery | Indication    | If indication is Other, specify |
|---|-------------------|---------------|---------------------------------|
| 15 NOV 2020                             | HEAD CT           | Adverse Event |                                 |
| 17 NOV 2020                             | HEAD CT           | Adverse Event |                                 |
| 10 DEC 2020                             | HEAD CT           | Adverse Event |                                 |

US3292103

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:20:34

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3292103

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:20:34

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3292103

Folder: SAE USA-US072-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

|  |  |
|--|--|
| SAEID  | USA-US072-2020-MRNA-1273-P301000013                              |
| Serious  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                      | DOUGLAS  |
| Investigator's Last Name                                       | DENHAM   |
| Site Address: Street   | 7940 FLOYD CURL DRIVE  |
| Site Address: City   | SAN ANTONIO  |
| Site Address: State  |  |
| Site Address: Postal Code                                      | 78229  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)                             | 2  |

US3292103

Folder: SAE USA-US072-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| SAEID   | USA-US072-2020-MRNA-1273-P301000013                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | DOUGLAS  |
| Investigator's Last Name  | DENHAM   |
| Site Address: Street  | 7940 FLOYD CURL DRIVE  |
| Site Address: City  | SAN ANTONIO  |
| Site Address: State   |  |
| Site Address: Postal Code   | 78229  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 2  |
| Date of submission (Pre-filled from custom function)  | 23/NOV/2020 18:38  |
| 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   |

US3292103

Folder: SAE USA-US072-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Feb 2021 18:45:06

Generated On: 09 Jun 2021 16:20:34

|   |  |
|---|--|
| SAEID   | USA-US072-2020-MRNA-1273-P301000013                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | DOUGLAS  |
| Investigator's Last Name  | DENHAM   |
| Site Address: Street  | 7940 FLOYD CURL DRIVE  |
| Site Address: City  | SAN ANTONIO  |
| Site Address: State   |  |
| Site Address: Postal Code   | 78229  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 2  |
| Date of submission (Pre-filled from custom function)  | 02/FEB/2021 17:24  |
| 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   |

Audit

US3292103 (Prod: Clinical Trials of Texas, Inc)



**US3292103**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:20:34**

[Participant ID](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)           | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 19 Jan 2021 21:12:01 |
| User entered 'US3292103'  | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 08 Aug 2020 22:15:31 |

**US3292103**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4)                | 09 Mar 2021 21:05:16 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 15:55:06 |

US3292103

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:20:34

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)                            | 09 Mar 2021 21:05:16 |
| User signature succeeded.  | Douglas Denham (b) (4)                      | 22 Feb 2021 18:45:09 |
| User entered '08 AUG 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 08 Aug 2020 22:15:32 |

**US3292103**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.            | (b) (4), (b) (6)       | 09 Mar 2021 21:05:16 |
| User signature succeeded.      | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6)       | 11 Aug 2020 15:55:06 |

**US3292103**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'SCRN' | System           | 11 Aug 2020 15:55:06 |

US3292103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:20:34

[Date of Birth \(MMM yyyy\)](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)                            | 09 Mar 2021 21:05:57 |
| User signature succeeded.  | Douglas Denham (b) (4)                      | 22 Feb 2021 18:45:07 |
| User entered (b) (6) 1955' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 08 Aug 2020 22:15:33 |

US3292103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:20:34

[Age](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:05:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '65'         | (b) (4), (b) (6)       | 11 Aug 2020 15:55:29 |

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:20:34**

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'YEARS' | System           | 11 Aug 2020 15:55:29 |



**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:20:34**

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '65' | System           | 08 Aug 2020 23:38:10 |

US3292103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:20:34

[Sex](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:05:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Female (F)' | (b) (4), (b) (6)       | 11 Aug 2020 15:55:29 |

US3292103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:20:34

[Ethnicity](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 09 Mar 2021 21:05:57 |
| User signature succeeded.                                      | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4), (b) (6)       | 11 Aug 2020 15:55:29 |

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:20:34**

[White](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:05:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'l'          | (b) (4), (b) (6)       | 11 Aug 2020 15:55:29 |

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:20:34**

[Black](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:05:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:55:29 |

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:20:34**

[Asian](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:05:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:55:29 |

US3292103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:20:34

[American Indian or Alaska Native](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:05:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:55:29 |

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:20:34**

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:05:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:55:29 |



**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:20:34**

[Other](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:05:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:55:29 |

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:20:34**

[If race is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:05:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 15:55:29 |

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:20:34**

[Unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:05:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:55:29 |

**US3292103**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:20:34**

[Not reported](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:05:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:55:29 |

US3292103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:20:34

Date of Informed Consent (dd MMM yyyy)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)                         | 09 Mar 2021 21:12:30 |
| User signature succeeded. | Douglas Denham (b) (4)                   | 22 Feb 2021 18:45:07 |
| User entered '8 Aug 2020' | (b) (4)<br>Darlington Akahara<br>(b) (4) | 08 Aug 2020 23:38:10 |

US3292103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:20:34

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Aug 2020' | System           | 08 Aug 2020 23:38:10 |

**US3292103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '2020' | System           | 08 Aug 2020 23:38:10 |

US3292103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:20:34

[Protocol Version](#)

| Audit                          | User                                     | Time (GMT)           |
|--------------------------------|--|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                         | 28 Apr 2021 21:02:25 |
| DataPoint Verified.            | (b) (4), (b) (6)                         | 09 Mar 2021 21:12:30 |
| User signature succeeded.      | Douglas Denham (b) (4)                   | 22 Feb 2021 18:45:07 |
| User entered 'Amendment 1 (1)' | (b) (4)<br>Darlington Akahara<br>(b) (4) | 08 Aug 2020 23:38:10 |



US3292103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:20:34

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

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)                         | 09 Mar 2021 21:12:30 |
| User signature succeeded. | Douglas Denham (b) (4)                   | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Darlington Akahara<br>(b) (4) | 08 Aug 2020 23:38:10 |

**US3292103**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)                         | 09 Mar 2021 21:12:30 |
| User signature succeeded. | Douglas Denham (b) (4)                   | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>Darlington Akahara<br>(b) (4) | 08 Aug 2020 23:38:10 |

US3292103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:20:34

If reason for screen fail is Other, specify

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)                         | 09 Mar 2021 21:12:30 |
| User signature succeeded. | Douglas Denham (b) (4)                   | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>Darlington Akahara<br>(b) (4) | 08 Aug 2020 23:38:10 |

US3292103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:20:34

[Was this participant screened previously?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)                         | 09 Mar 2021 21:12:30 |
| User signature succeeded. | Douglas Denham (b) (4)                   | 22 Feb 2021 18:45:07 |
| User entered 'No (N)'     | (b) (4)<br>Darlington Akahara<br>(b) (4) | 08 Aug 2020 23:38:10 |

US3292103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:20:34

[If Yes, previous participant number](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)                            | 09 Mar 2021 21:12:30 |
| User signature succeeded. | Douglas Denham (b) (4)                      | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 08 Aug 2020 22:15:32 |

US3292103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:20:34

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'l'  | System           | 08 Aug 2020 23:38:24 |

US3292103

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:20:34

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

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)                         | 09 Mar 2021 21:28:13 |
| User signature succeeded. | Douglas Denham (b) (4)                   | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Darlington Akahara<br>(b) (4) | 08 Aug 2020 23:38:24 |

**US3292103**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 16:20:34**

[Were any significant conditions reported?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:29:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 15:55:34 |



US3292103

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:20:34

[Condition](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 09 Mar 2021 21:31:28 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0. | Coder Import (b) (4)   | 14 Aug 2020 07:16:20 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4)   | 14 Aug 2020 07:16:20 |
| Data point term sent to Coder   | System                 | 11 Aug 2020 15:57:21 |
| User entered 'environmental cedar allergy'  | (b) (4), (b) (6)       | 11 Aug 2020 15:57:03 |

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 09 Mar 2021 21:31:28 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'UN UNK 1990' reason for change:<br>Data Entry Error | (b) (4), (b) (6)       | 11 Aug 2020 16:22:39 |
| User entered 'un UNK 1996'  | (b) (4), (b) (6)       | 11 Aug 2020 15:57:03 |

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:31:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:57:03 |

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:31:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 15:57:03 |

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:31:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 15:57:03 |

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:31:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:57:03 |

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 1990' | System           | 11 Aug 2020 16:22:39 |
| User entered 'Jan 1996' | System           | 11 Aug 2020 15:57:03 |

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1990' | System           | 11 Aug 2020 16:22:39 |
| User entered '1996' | System           | 11 Aug 2020 15:57:03 |



US3292103

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:20:34

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 15:57:03 |

**US3292103**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 15:57:03 |

US3292103

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:20:34

Condition

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 09 Mar 2021 21:34:07 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Medical device implantation, LLT: Insertion of surgical hardware - version MedDRA\23.0. | Coder Import (b) (4)   | 14 Aug 2020 09:42:12 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4)   | 14 Aug 2020 09:42:12 |
| Data point term sent to Coder   | System                 | 11 Aug 2020 15:58:25 |
| User entered 'Harrington rod implant'   | (b) (4), (b) (6)       | 11 Aug 2020 15:57:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:34:07 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 1974' | (b) (4), (b) (6)       | 11 Aug 2020 15:57:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:34:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:57:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:34:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 15:57:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:34:07 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 1974' | (b) (4), (b) (6)       | 11 Aug 2020 15:57:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:34:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:57:49 |



**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 1974' | System           | 11 Aug 2020 15:57:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1974' | System           | 11 Aug 2020 15:57:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 1974' | System           | 11 Aug 2020 15:57:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1974' | System           | 11 Aug 2020 15:57:49 |

US3292103

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:20:34

[Condition](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)                | 09 Mar 2021 21:34:36 |
| User signature succeeded.  | Douglas Denham (b) (4)          | 22 Feb 2021 18:45:09 |
| User closed query 'Per DM CLR: Please specify the location where the TOTAL HIP REPLACEMENT was performed (e.g. right, left or both hips). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).   | (b) (4),<br>(b) (6)             | 30 Oct 2020 20:56:05 |
| Query 'Per DM CLR: Please specify the location where the TOTAL HIP REPLACEMENT was performed (e.g. right, left or both hips). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'total hip replacement, correct as entered, both hips.' (Site from DM). |                                 | 21 Sep 2020 18:12:08 |
| User opened query 'Per DM CLR: Please specify the location where the TOTAL HIP REPLACEMENT was performed (e.g. right, left or both hips). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).   |                                 | 17 Sep 2020 19:47:29 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Total hip replacement - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 15:59:14 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)            | 11 Aug 2020 15:59:14 |
| Data point term sent to Coder  | System                          | 11 Aug 2020 15:58:26 |
| User entered 'Total hip replacement'   | (b) (4), (b) (6)                | 11 Aug 2020 15:58:10 |

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:34:36 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 1999' | (b) (4), (b) (6)       | 11 Aug 2020 15:58:10 |

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:34:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:58:10 |

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:34:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 15:58:10 |



**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:34:36 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 1999' | (b) (4), (b) (6)       | 11 Aug 2020 15:58:10 |

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:20:34**

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:34:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:58:10 |

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 1999' | System           | 11 Aug 2020 15:58:10 |

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1999' | System           | 11 Aug 2020 15:58:10 |

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 1999' | System           | 11 Aug 2020 15:58:10 |

**US3292103**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1999' | System           | 11 Aug 2020 15:58:10 |

US3292103

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:20:34

[Condition](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)                | 09 Mar 2021 21:36:49 |
| User signature succeeded.  | Douglas Denham (b) (4)          | 22 Feb 2021 18:45:09 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 11 Aug 2020 16:00:14 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)            | 11 Aug 2020 16:00:14 |
| Data point term sent to Coder  | System                          | 11 Aug 2020 15:59:27 |
| User entered 'C-Section'   | (b) (4), (b) (6)                | 11 Aug 2020 15:58:35 |

US3292103

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:20:34

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:36:49 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un Apr 1984' | (b) (4), (b) (6)       | 11 Aug 2020 15:58:35 |



**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:36:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:58:35 |

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:36:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 15:58:35 |

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:36:49 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un Apr 1984' | (b) (4), (b) (6)       | 11 Aug 2020 15:58:35 |

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:20:34**

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:36:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:58:35 |

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Apr 1984' | System           | 11 Aug 2020 15:58:35 |

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1984' | System           | 11 Aug 2020 15:58:35 |

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Apr 1984' | System           | 11 Aug 2020 15:58:35 |

**US3292103**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1984' | System           | 11 Aug 2020 15:58:35 |



US3292103

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:20:34

[Condition](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)                | 09 Mar 2021 21:36:52 |
| User signature succeeded.  | Douglas Denham (b) (4)          | 22 Feb 2021 18:45:09 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 11 Aug 2020 16:00:16 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)            | 11 Aug 2020 16:00:16 |
| Data point term sent to Coder  | System                          | 11 Aug 2020 15:59:28 |
| User entered 'C-Section'   | (b) (4), (b) (6)                | 11 Aug 2020 15:59:02 |

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:36:52 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un Aug 1988' | (b) (4), (b) (6)       | 11 Aug 2020 15:59:02 |

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:36:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:59:02 |

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:36:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 15:59:02 |

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:36:52 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un Aug 1988' | (b) (4), (b) (6)       | 11 Aug 2020 15:59:02 |

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:20:34**

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:36:52 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:59:02 |

US3292103

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:20:34

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Aug 1988' | System           | 11 Aug 2020 15:59:02 |

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:20:34**

**Start Year (derived)**

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1988' | System           | 11 Aug 2020 15:59:02 |



US3292103

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:20:34

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Aug 1988' | System           | 11 Aug 2020 15:59:02 |

**US3292103**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1988' | System           | 11 Aug 2020 15:59:02 |

US3292103

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:20:34

Condition

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 09 Mar 2021 21:37:09 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User closed query 'Per DM CLR: Please specify the location where the DECREASED VISUAL ACUITY is affecting (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).             | (b) (4), (b) (6)       | 08 Oct 2020 09:50:10 |
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\23.0.  | Coder Import (b) (4)   | 21 Sep 2020 18:13:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)   | 21 Sep 2020 18:13:53 |
| Data point term sent to Coder  | System                 | 21 Sep 2020 18:12:52 |
| Query 'Per DM CLR: Please specify the location where the DECREASED VISUAL ACUITY is affecting (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM). | (b) (4), (b) (6)       | 21 Sep 2020 18:12:33 |
| Coding entries removed.  |                        | 21 Sep 2020 18:12:27 |
| User entered 'Bilateral DECREASED VISUAL ACUITY' reason for change: Data Entry Error   |                        | 21 Sep 2020 18:12:27 |
| User opened query 'Per DM CLR: Please specify the location where the DECREASED VISUAL ACUITY is affecting (e.g. right, left or both eyes). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).             |                        | 17 Sep 2020 19:38:59 |

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:20:34

[Condition](#)

| Audit  | User                 | Time (GMT)           |
|--|----------------------|----------------------|
| User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual acuity reduced, LLT: Visual acuity decreased - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Aug 2020 16:01:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4) | 11 Aug 2020 16:01:20 |
| Data point term sent to Coder  | System               | 11 Aug 2020 16:00:29 |
| User entered 'Decreased visual acuity'   | (b) (4), (b) (6)     | 11 Aug 2020 15:59:29 |

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:37:09 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 1963' | (b) (4), (b) (6)       | 11 Aug 2020 15:59:29 |

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:37:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:59:29 |

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:37:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 15:59:29 |

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:37:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 15:59:29 |



**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:20:34**

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:37:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:59:29 |

US3292103

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:20:34

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 1963' | System           | 11 Aug 2020 15:59:29 |

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1963' | System           | 11 Aug 2020 15:59:29 |

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 15:59:29 |

**US3292103**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 15:59:29 |

US3292103

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:20:34

[Condition](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 28 Apr 2021 21:02:25 |
| DataPoint Verified.   | (b) (4), (b) (6)                | 09 Mar 2021 21:38:24 |
| User signature succeeded.   | Douglas Denham (b) (4)          | 22 Feb 2021 18:45:09 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 11 Aug 2020 16:01:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)            | 11 Aug 2020 16:01:20 |
| Data point term sent to Coder   | System                          | 11 Aug 2020 16:00:31 |
| User entered 'Hypercholersterolemia'  | (b) (4), (b) (6)                | 11 Aug 2020 15:59:50 |

US3292103

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:20:34

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:38:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 2015' | (b) (4), (b) (6)       | 11 Aug 2020 15:59:50 |

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:38:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:59:50 |



**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:38:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 15:59:50 |

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:38:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 15:59:50 |

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:20:34**

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:38:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 15:59:50 |

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 2015' | System           | 11 Aug 2020 15:59:50 |

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '2015' | System           | 11 Aug 2020 15:59:50 |

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 15:59:50 |

**US3292103**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 15:59:50 |

US3292103

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:20:34

[Condition](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 28 Apr 2021 21:02:25 |
| DataPoint Verified.   | (b) (4), (b) (6)                | 09 Mar 2021 21:38:56 |
| User signature succeeded.   | Douglas Denham (b) (4)          | 22 Feb 2021 18:45:09 |
| 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. | (b) (4)<br>Coder Import (b) (4) | 11 Aug 2020 16:01:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)            | 11 Aug 2020 16:01:42 |
| Data point term sent to Coder   | System                          | 11 Aug 2020 16:00:31 |
| User entered 'Hypertension'   | (b) (4), (b) (6)                | 11 Aug 2020 16:00:10 |



**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:38:56 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 2005' | (b) (4), (b) (6)       | 11 Aug 2020 16:00:10 |

**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:38:56 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:00:10 |

**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:38:56 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:00:10 |

**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:38:56 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:00:10 |

**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:20:34**

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:38:56 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:00:10 |

US3292103

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:20:34

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 2005' | System           | 11 Aug 2020 16:00:10 |

**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '2005' | System           | 11 Aug 2020 16:00:10 |

US3292103

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:20:34

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 16:00:10 |



**US3292103**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 16:00:10 |

US3292103

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:20:34

Condition

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)                | 09 Mar 2021 21:40:16 |
| User signature succeeded.  | Douglas Denham (b) (4)          | 22 Feb 2021 18:45:09 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Esophageal reflux - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 12 Aug 2020 13:31:22 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)            | 12 Aug 2020 13:31:22 |
| Data point term sent to Coder  | System                          | 11 Aug 2020 16:01:32 |
| User entered 'esophageal reflux (GERD)'  | (b) (4), (b) (6)                | 11 Aug 2020 16:00:34 |

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:40:16 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 2000' | (b) (4), (b) (6)       | 11 Aug 2020 16:00:34 |

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:40:16 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:00:34 |

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:40:16 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:00:34 |

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:40:16 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:00:34 |

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:20:34**

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:40:16 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:00:34 |

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 2000' | System           | 11 Aug 2020 16:00:34 |



**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '2000' | System           | 11 Aug 2020 16:00:34 |

US3292103

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:20:34

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 16:00:34 |

**US3292103**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 16:00:34 |

US3292103

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:20:34

[Condition](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 09 Mar 2021 21:40:30 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0. | Coder Import (b) (4)   | 11 Aug 2020 16:02:09 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)   | 11 Aug 2020 16:02:09 |
| Data point term sent to Coder   | System                 | 11 Aug 2020 16:01:33 |
| User entered 'Hypothyroid'  | (b) (4), (b) (6)       | 11 Aug 2020 16:00:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:40:30 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 2015' | (b) (4), (b) (6)       | 11 Aug 2020 16:00:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:40:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:00:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:40:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:00:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:40:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:00:49 |



**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:20:34**

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:40:30 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:00:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 2015' | System           | 11 Aug 2020 16:00:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '2015' | System           | 11 Aug 2020 16:00:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 16:00:49 |

**US3292103**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 16:00:49 |

US3292103

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:20:34

[Condition](#)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 28 Apr 2021 21:02:25 |
| DataPoint Verified.   | (b) (4), (b) (6)           | 09 Mar 2021 21:43:18 |
| User signature succeeded.   | Douglas Denham (b) (4)     | 22 Feb 2021 18:45:09 |
| User closed query 'Per DM CLR: Please update the condition to include the location of Joint Pain (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).             | (b) (4), (b) (6)           | 08 Oct 2020 09:50:44 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\23.0.   | Coder Import (b) (4)       | 24 Sep 2020 18:37:09 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4)       | 24 Sep 2020 18:37:09 |
| Data point term sent to Coder   | System                     | 24 Sep 2020 16:17:49 |
| Query 'Per DM CLR: Please update the condition to include the location of Joint Pain (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) | 24 Sep 2020 16:16:53 |
| Coding entries removed.   | Victoria Hernandez (b) (4) | 24 Sep 2020 16:16:48 |
| User entered 'CHRONIC GENERALIZED JOINT PAIN' reason for change: Data Entry Error   | Victoria Hernandez (b) (4) | 24 Sep 2020 16:16:48 |
| User opened query 'Per DM CLR: Please update the condition to include the location of Joint Pain (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).             | (b) (4), (b) (6)           | 17 Sep 2020 19:39:49 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint pain - version MedDRA\23.0.   | Coder Import (b) (4)       | 13 Aug 2020 15:43:37 |

US3292103

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:20:34

[Condition](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User coded data point as Term Coded data point by | Coder Import (b) (4) | 13 Aug 2020 15:43:37 |
| User: (b) (6) - version MedDRA\23.0.              | (b) (4)              |                      |
| Data point term sent to Coder                     | System               | 11 Aug 2020 16:01:33 |
| User entered 'chronic joint pain'                 | (b) (4), (b) (6)     | 11 Aug 2020 16:01:07 |

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:43:18 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 2000' | (b) (4), (b) (6)       | 11 Aug 2020 16:01:07 |



**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:43:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:01:07 |

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:43:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:01:07 |

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:43:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:01:07 |

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:20:34**

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:43:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:01:07 |

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 2000' | System           | 11 Aug 2020 16:01:07 |

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '2000' | System           | 11 Aug 2020 16:01:07 |

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 16:01:07 |

**US3292103**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 16:01:07 |



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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:20:34

Condition

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 25 Mar 2021 20:16:44 |
| User closed query 'Please add laterality to source.' (Site from CRA).  | (b) (4), (b) (6)       | 25 Mar 2021 20:16:42 |
| Query 'Please add laterality to source.' answered with 'updated' (Site from CRA).  | Dawn Killian (b) (4)   | 23 Mar 2021 18:27:14 |
| User opened query 'Please add laterality to source.' (Site from CRA).  | (b) (4), (b) (6)       | 09 Mar 2021 21:46:37 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User closed query 'Per CDM: Please confirm if participant is treating condition with medication. If yes, update the Concomitant medication eCRF or provide an explanation for no medical treatment.' (Site from DM).   | (b) (4), (b) (6)       | 30 Nov 2020 09:28:52 |
| Query 'Per CDM: Please confirm if participant is treating condition with medication. If yes, update the Concomitant medication eCRF or provide an explanation for no medical treatment.' answered with 'patient is not prescribed to take medication for this condition' (Site from DM). | Kevin Martinez (b) (4) | 04 Nov 2020 22:43:17 |
| User opened query 'Per CDM: Please confirm if participant is treating condition with medication. If yes, update the Concomitant medication eCRF or provide an explanation for no medical treatment.' (Site from DM).   | (b) (4), (b) (6)       | 02 Nov 2020 14:29:30 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).        | (b) (4), (b) (6)       | 02 Nov 2020 14:29:30 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\23.0.  | Coder Import (b) (4)   | 24 Sep 2020 21:51:43 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.   | Coder Import (b) (4)   | 24 Sep 2020 21:51:43 |
| Data point term sent to Coder  | System                 | 24 Sep 2020 16:19:55 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:20:34

Condition

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'UPDATED' (Site from DM). Coding entries removed. | Victoria Hernandez (b) (4) | 24 Sep 2020 16:19:30 |
| User entered 'BILATERAL HIP RHEUMATOID ARTHRITIS' reason for change: Data Entry Error   | Victoria Hernandez (b) (4) | 24 Sep 2020 16:19:25 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).                                     | Victoria Hernandez (b) (4) | 24 Sep 2020 16:19:25 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\\23.0.  | (b) (4), (b) (6)           | 17 Sep 2020 19:41:27 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)       | 11 Aug 2020 16:02:10 |
| Data point term sent to Coder   | (b) (4)                    | 11 Aug 2020 16:02:10 |
| User entered 'rheumatoid arthritis'   | System                     | 11 Aug 2020 16:01:33 |
|   | (b) (4), (b) (6)           | 11 Aug 2020 16:01:33 |

**US3292103**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:47:32 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 1967' | (b) (4), (b) (6)       | 11 Aug 2020 16:01:33 |

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:20:34

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:47:34 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:01:33 |

**US3292103**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:47:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:01:33 |

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:20:34

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

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)           | 28 Apr 2021 21:02:25 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 08 Apr 2021 16:13:33 |
| DataPoint Verified.  | (b) (4), (b) (6)           | 25 Mar 2021 20:16:40 |
| User closed query 'Per source, end date is UN UNK 1999. Please review and reconcile.' (Site from CRA).   | (b) (4), (b) (6)           | 25 Mar 2021 20:16:36 |
| Query 'Per source, end date is UN UNK 1999. Please review and reconcile.' answered with 'updated' (Site from CRA).   | Dawn Killian (b) (4)       | 23 Mar 2021 18:27:56 |
| Signature has been broken.   | Dawn Killian (b) (4)       | 23 Mar 2021 18:27:51 |
| User entered 'UN UNK 1999' reason for change:  | (b) (4)                    |                      |
| Data Entry Error   | Dawn Killian (b) (4)       | 23 Mar 2021 18:27:51 |
| User opened query 'Per source, end date is UN UNK 1999. Please review and reconcile.' (Site from CRA).   | (b) (4), (b) (6)           | 09 Mar 2021 21:48:12 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 22 Feb 2021 18:45:09 |
| Query 'Per CDM: Response noted however it appears updates are incomplete. Since, stop date has been removed, please confirm if this condition is Ongoing and if yes, update appropriately.' canceled (Site from DM).                           | (b) (4), (b) (6)           | 03 Nov 2020 22:26:13 |
| User opened query 'Per CDM: Response noted however it appears updates are incomplete. Since, stop date has been removed, please confirm if this condition is Ongoing and if yes, update appropriately.' (Site from DM).                        |                            | 02 Nov 2020 14:16:36 |
| User closed query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).             |                            | 02 Nov 2020 14:16:36 |
| Query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) | 24 Sep 2020 16:19:35 |
| User entered empty; reason for change Data Entry Error   | Victoria Hernandez (b) (4) | 24 Sep 2020 16:19:25 |

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:20:34

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User opened query 'Per DM CLR: Please review the stop date of this Chronic MH condition, as this condition is not expected to resolve. Please review and update stop date if appropriate or provide explanation. ' (Site from DM).<br>User entered 'un UNK 1999' | (b) (4), (b) (6) | 17 Sep 2020 19:41:46 |
|  | (b) (4), (b) (6) | 11 Aug 2020 16:01:33 |

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:20:34

[Stop date completely unknown](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)           | 28 Apr 2021 21:02:25 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 08 Apr 2021 16:13:33 |
| DataPoint Verified.  | (b) (4), (b) (6)           | 25 Mar 2021 20:16:38 |
| User closed query 'Per source, end date is UN UNK 1999. Please review and reconcile.' (Site from CRA).             | (b) (4), (b) (6)           | 25 Mar 2021 20:16:34 |
| Query 'Per source, end date is UN UNK 1999. Please review and reconcile.' answered with 'updated' (Site from CRA). | Dawn Killian (b) (4)       | 23 Mar 2021 18:28:00 |
| Signature has been broken.   | (b) (4)                    |                      |
|  | Dawn Killian (b) (4)       | 23 Mar 2021 18:27:51 |
| User entered '0' reason for change: Data Entry Error   | (b) (4)                    |                      |
|  | Dawn Killian (b) (4)       | 23 Mar 2021 18:27:51 |
| User opened query 'Per source, end date is UN UNK 1999. Please review and reconcile.' (Site from CRA).             | (b) (4)                    |                      |
| User signature succeeded.  | (b) (4), (b) (6)           | 09 Mar 2021 21:48:27 |
|  | Douglas Denham (b) (4)     | 22 Feb 2021 18:45:09 |
| User entered '1' reason for change: Data Entry Error   | (b) (4)                    |                      |
|  | Victoria Hernandez (b) (4) | 24 Sep 2020 16:19:25 |
| User entered '0'   | (b) (4)                    |                      |
|  | (b) (4), (b) (6)           | 11 Aug 2020 16:01:33 |



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**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 1967' | System           | 11 Aug 2020 16:01:33 |

**US3292103**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1967' | System           | 11 Aug 2020 16:01:33 |

**US3292103**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 1999' | System           | 23 Mar 2021 18:27:51 |
| User entered empty.     | System           | 24 Sep 2020 16:19:25 |
| User entered 'Jan 1999' | System           | 11 Aug 2020 16:01:33 |

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:20:34

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1999' | System           | 23 Mar 2021 18:27:51 |
| User entered empty. | System           | 24 Sep 2020 16:19:25 |
| User entered '1999' | System           | 11 Aug 2020 16:01:33 |

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:20:34

[Condition](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 09 Mar 2021 21:52:15 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Scoliosis, LLT: Scoliosis - version MedDRA\23.0. | Coder Import (b) (4)   | 11 Aug 2020 16:03:11 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)   | 11 Aug 2020 16:03:11 |
| Data point term sent to Coder  | System                 | 11 Aug 2020 16:02:34 |
| User entered 'scoliosis'   | (b) (4), (b) (6)       | 11 Aug 2020 16:02:05 |

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:52:15 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 1974' | (b) (4), (b) (6)       | 11 Aug 2020 16:02:05 |

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:52:15 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:02:05 |

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:52:15 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:02:05 |



**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:52:15 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 1974' | (b) (4), (b) (6)       | 11 Aug 2020 16:02:05 |

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:20:34**

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:52:15 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:02:05 |

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 1974' | System           | 11 Aug 2020 16:02:05 |

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1974' | System           | 11 Aug 2020 16:02:05 |

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 1974' | System           | 11 Aug 2020 16:02:05 |

**US3292103**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '1974' | System           | 11 Aug 2020 16:02:05 |

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Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:20:34

[Condition](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 09 Mar 2021 21:52:32 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User coded data point as SOC: Investigations, HLGT: Endocrine investigations (incl sex hormones), HLT: Reproductive hormone analyses, PT: Progesterone decreased, LLT: Progesterone decreased - version MedDRA\\23.0. | Coder Import (b) (4)   | 16 Aug 2020 10:45:09 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)   | 16 Aug 2020 10:45:09 |
| Data point term sent to Coder   | System                 | 11 Aug 2020 16:02:35 |
| User entered 'low progesterone'   | (b) (4), (b) (6)       | 11 Aug 2020 16:02:19 |

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 21:52:32 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'un UNK 2015' | (b) (4), (b) (6)       | 11 Aug 2020 16:02:19 |



**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:52:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:02:19 |

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:20:34**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:52:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:02:19 |

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:52:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:02:19 |

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:20:34**

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 21:52:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:02:19 |

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 2015' | System           | 11 Aug 2020 16:02:19 |

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '2015' | System           | 11 Aug 2020 16:02:19 |

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 16:02:19 |

**US3292103**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 11 Aug 2020 16:02:19 |



US3292103

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:20:34

[Condition](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 09 Mar 2021 21:55:55 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User closed query 'Per CDM: Please review, Start date of MH = UN UNK 2000. However, Post-menopausal date recorded in Childbearing ecf is UN UNK 2007. Review and reconcile dates as appropriate. Ensure all details are recorded in the CB eCRF for appropriate match' (Site from DM).   | (b) (4), (b) (6)       | 15 Dec 2020 08:10:31 |
| Query 'Per CDM: Please review, Start date of MH = UN UNK 2000. However, Post-menopausal date recorded in Childbearing ecf is UN UNK 2007. Review and reconcile dates as appropriate. Ensure all details are recorded in the CB eCRF for appropriate match' answered with 'updated' (Site from DM).   | Dawn Killian (b) (4)   | 09 Dec 2020 21:56:40 |
| User opened query 'Per CDM: Please review, Start date of MH = UN UNK 2000. However, Post-menopausal date recorded in Childbearing ecf is UN UNK 2007. Review and reconcile dates as appropriate. Ensure all details are recorded in the CB eCRF for appropriate match' (Site from DM).   | (b) (4), (b) (6)       | 25 Nov 2020 09:47:39 |
| User closed query 'Per DM CLR: Please review response to Is the Event/Condition Ongoing? = NO. As this condition's stop date is unexpected, please verify status of this condition and consider updating response to Is the Event/Condition Ongoing, as applicable. Also, Please note, Start date of MH = UN UNK 2000. However, Post-menopausal date recorded in Childbearing ecf is UN UNK 2007. Review and reconcile dates as appropriate. Ensure all details are recorded in the CB eCRF for appropriate match' (Site from DM). | (b) (4), (b) (6)       | 25 Nov 2020 09:47:39 |

US3292103

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:20:34

Condition

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Query 'Per DM CLR: Please review response to Is the Event/Condition Ongoing? = NO. As this condition's stop date is unexpected, please verify status of this condition and consider updating response to Is the Event/Condition Ongoing, as applicable. Also, Please note, Start date of MH = UN UNK 2000. However, Post-menopausal date recorded in Childbearing ecf is UN UNK 2007. Review and reconcile dates as appropriate. Ensure all details are recorded in the CB eCRF for appropriate match' answered with 'update' (Site from DM). | Dawn Killian (b) (4)       | 20 Oct 2020 19:14:25 |
| User opened query 'Per DM CLR: Please review response to Is the Event/Condition Ongoing? = NO. As this condition's stop date is unexpected, please verify status of this condition and consider updating response to Is the Event/Condition Ongoing, as applicable. Also, Please note, Start date of MH = UN UNK 2000. However, Post-menopausal date recorded in Childbearing ecf is UN UNK 2007. Review and reconcile dates as appropriate. Ensure all details are recorded in the CB eCRF for appropriate match' (Site from DM).            | (b) (4), (b) (6)           | 19 Oct 2020 03:03:20 |
| User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.  | Coder Import (b) (4)       | 22 Sep 2020 20:59:46 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)       | 22 Sep 2020 20:59:46 |
| Data point term sent to Coder   | System                     | 22 Sep 2020 20:58:33 |
| User entered 'POST MENOPAUSAL'  | Victoria Hernandez (b) (4) | 22 Sep 2020 20:58:09 |

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.                             | (b) (4), (b) (6)           | 28 Apr 2021 21:02:25 |
| DataPoint Verified.                           | (b) (4), (b) (6)           | 09 Mar 2021 21:55:55 |
| User signature succeeded.                     | Douglas Denham (b) (4)     | 22 Feb 2021 18:45:09 |
| User entered 'UN UNK 2007' reason for change: | (b) (4)                    |                      |
| Data Entry Error                              | Dawn Killian (b) (4)       | 09 Dec 2020 21:56:34 |
| User entered 'UN UNK 2000'                    | (b) (4)                    |                      |
|   | Victoria Hernandez (b) (4) | 22 Sep 2020 20:58:09 |
|   | (b) (4)                    |                      |

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                                  | Time (GMT)           |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                      | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)                      | 09 Mar 2021 21:55:55 |
| User signature succeeded. | Douglas Denham (b) (4)                | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4)<br>Victoria Hernandez (b) (4) | 22 Sep 2020 20:58:09 |

US3292103

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:20:34

[Condition ongoing at study entry](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)           | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)           | 09 Mar 2021 21:55:55 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | (b) (4)                    |                      |
|  | Dawn Killian (b) (4)       | 20 Oct 2020 19:14:21 |
|  | (b) (4)                    |                      |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                     | 22 Sep 2020 20:58:25 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                     | 22 Sep 2020 20:58:25 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Victoria Hernandez (b) (4) | 22 Sep 2020 20:58:25 |
|  | (b) (4)                    |                      |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                     | 22 Sep 2020 20:58:09 |
| User entered empty.  | Victoria Hernandez (b) (4) | 22 Sep 2020 20:58:09 |
|  | (b) (4)                    |                      |

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                                  | Time (GMT)           |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                      | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)                      | 09 Mar 2021 21:55:55 |
| User signature succeeded. | Douglas Denham (b) (4)                | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4)<br>Victoria Hernandez (b) (4) | 22 Sep 2020 20:58:09 |

US3292103

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:20:34

[Stop date completely unknown](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)           | 28 Apr 2021 21:02:25 |
| DataPoint Verified.                                  | (b) (4), (b) (6)           | 09 Mar 2021 21:55:55 |
| User signature succeeded.                            | Douglas Denham (b) (4)     | 22 Feb 2021 18:45:09 |
| User entered '0' reason for change: Data Entry Error | (b) (4)                    |                      |
|  | Dawn Killian (b) (4)       | 20 Oct 2020 19:14:21 |
|  | (b) (4)                    |                      |
| User entered '1'                                     | Victoria Hernandez (b) (4) | 22 Sep 2020 20:58:09 |
|  | (b) (4)                    |                      |

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'Jan 2007' | System           | 09 Dec 2020 21:56:34 |
| User entered 'Jan 2000' | System           | 22 Sep 2020 20:58:09 |



**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '2007' | System           | 09 Dec 2020 21:56:34 |
| User entered '2000' | System           | 22 Sep 2020 20:58:09 |

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 22 Sep 2020 20:58:09 |

**US3292103**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered empty. | System           | 22 Sep 2020 20:58:09 |

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:03:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:03:07 |

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 22:03:18 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '08 Aug 2020' | (b) (4), (b) (6)       | 11 Aug 2020 16:03:07 |

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

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

| Audit  | User                   | Time (GMT)                            |
|--|------------------------|---------------------------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25                  |
| DataPoint Verified.  | (b) (4), (b) (6)       | 09 Mar 2021 22:03:18                  |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09                  |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)                | (b) (4), (b) (6) 24 Aug 2020 15:10:55 |
| User entered '16:05' reason for change: Data Entry Error                                     |                        | 14 Aug 2020 17:30:12                  |
| Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System). |                        | 11 Aug 2020 16:03:13                  |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 11 Aug 2020 16:03:07                  |
| User entered empty.  | (b) (4), (b) (6)       | 11 Aug 2020 16:03:07                  |

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered '08 Aug 2020 16:05' | System           | 14 Aug 2020 17:30:12 |
| User entered empty.              | System           | 11 Aug 2020 16:03:07 |

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:03:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '159.3' cm   | (b) (4), (b) (6)       | 11 Aug 2020 16:03:07 |
| DataPoint set to visible. | System                 | 08 Aug 2020 23:38:24 |



**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:03:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '62.9' kg    | (b) (4), (b) (6)       | 11 Aug 2020 16:03:07 |
| DataPoint set to visible. | System                 | 08 Aug 2020 23:38:24 |

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

BMI (xxx.x)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| Amendment Manager: User entered '24.78672' | System           | 16 Sep 2020 23:49:13 |
| User entered '24.8'                        | System           | 11 Aug 2020 16:03:07 |
| DataPoint set to visible.                  | System           | 08 Aug 2020 23:38:24 |

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'kg/m2'      | System           | 11 Aug 2020 16:03:07 |
| DataPoint set to visible. | System           | 08 Aug 2020 23:38:24 |

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Temperature (xxx.x)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 09 Mar 2021 22:03:18 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4), (b) (6)       | 24 Aug 2020 15:10:59 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                  | (b) (4), (b) (6)       | 13 Aug 2020 19:43:26 |
| Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System). | (b) (4), (b) (6)       | 11 Aug 2020 16:03:16 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 11 Aug 2020 16:03:07 |
| User entered empty.  | (b) (4), (b) (6)       | 11 Aug 2020 16:03:07 |

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

[Route of measurement](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 09 Mar 2021 22:03:18 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4), (b) (6)       | 24 Aug 2020 17:09:27 |
| User entered empty; reason for change Data Entry Error                                       |                        | 14 Aug 2020 01:25:06 |
| User entered 'Other (Other)' reason for change: Data Entry Error                             |                        | 13 Aug 2020 19:43:26 |
| Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System). | (b) (4), (b) (6)       | 11 Aug 2020 16:03:19 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 11 Aug 2020 16:03:07 |
| User entered empty.  | (b) (4), (b) (6)       | 11 Aug 2020 16:03:07 |

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[If Other, specify](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 09 Mar 2021 22:03:18 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty; reason for change Data Entry Error                      | (b) (4), (b) (6)       | 14 Aug 2020 01:25:06 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)       | 13 Aug 2020 19:43:26 |
| User entered empty.   | (b) (4), (b) (6)       | 11 Aug 2020 16:03:07 |

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

[Pulse \(xxx\)](#)

| Audit  | User                   | Time (GMT)                            |
|--|------------------------|---------------------------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25                  |
| DataPoint Verified.  | (b) (4), (b) (6)       | 09 Mar 2021 22:03:18                  |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09                  |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)                | (b) (4), (b) (6) 24 Aug 2020 15:11:09 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                  |                        | 13 Aug 2020 19:43:26                  |
| Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System). |                        | 11 Aug 2020 16:03:21                  |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 11 Aug 2020 16:03:07                  |
| User entered empty.  | (b) (4), (b) (6)       | 11 Aug 2020 16:03:07                  |

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'bpm'  | System           | 13 Aug 2020 19:43:26 |
| User entered empty. | System           | 11 Aug 2020 16:03:07 |



US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

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

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 09 Mar 2021 22:03:18 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4), (b) (6)       | 24 Aug 2020 15:11:23 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                  | (b) (4), (b) (6)       | 13 Aug 2020 19:43:26 |
| Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System). | (b) (4), (b) (6)       | 11 Aug 2020 16:03:22 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 11 Aug 2020 16:03:07 |
| User entered empty.  | (b) (4), (b) (6)       | 11 Aug 2020 16:03:07 |

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'breaths/min' | System           | 13 Aug 2020 19:43:26 |
| User entered empty.        | System           | 11 Aug 2020 16:03:07 |

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Systolic Blood Pressure (xxx)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 09 Mar 2021 22:03:18 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4)                | 4 Aug 2020 15:11:27  |
| User entered missing code ND - Not Done; reason for change Data Entry Error                  | (b) (4), (b) (6)       | 3 Aug 2020 19:43:26  |
| Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System). | (b) (4), (b) (6)       | 1 Aug 2020 16:03:26  |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 11 Aug 2020 16:03:07 |
| User entered empty.  | (b) (4), (b) (6)       | 11 Aug 2020 16:03:07 |

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'mmHg' | System           | 13 Aug 2020 19:43:26 |
| User entered empty. | System           | 11 Aug 2020 16:03:07 |

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Diastolic Blood Pressure (xxx)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 09 Mar 2021 22:03:18 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User closed query 'Data is required. Please provide.' (Site from System).                    | (b) (4), (b) (6)       | 24 Aug 2020 15:11:33 |
| User entered missing code ND - Not Done; reason for change Data Entry Error                  | (b) (4), (b) (6)       | 13 Aug 2020 19:43:26 |
| Query 'Data is required. Please provide.' answered with 'combined visit' (Site from System). | (b) (4), (b) (6)       | 11 Aug 2020 16:03:28 |
| User opened query 'Data is required. Please provide.' (Site from System).                    | System                 | 11 Aug 2020 16:03:07 |
| User entered empty.  | (b) (4), (b) (6)       | 11 Aug 2020 16:03:07 |

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |
| User entered 'mmHg' | System           | 13 Aug 2020 19:43:26 |
| User entered empty. | System           | 11 Aug 2020 16:03:07 |

**US3292103**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |

US3292103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 21:02:25 |



US3292103

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:20:34

[Was the physical examination performed?](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 09 Mar 2021 22:06:14 |
| User signature succeeded.                                  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6)       | 14 Aug 2020 01:25:26 |
| User entered 'No (N)'                                      | (b) (4), (b) (6)       | 11 Aug 2020 16:03:32 |

US3292103

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:20:34

Date of examination (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 09 Mar 2021 22:06:14 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).    | (b) (4), (b) (6)       | 07 Sep 2020 09:11:59 |
| User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System). |                        | 05 Sep 2020 19:14:02 |
| User entered '8 Aug 2020' reason for change: Data Entry Error  | (b) (4), (b) (6)       | 14 Aug 2020 01:25:26 |
| User entered empty.  | (b) (4), (b) (6)       | 11 Aug 2020 16:03:32 |

US3292103

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:20:34

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 22:07:36 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '08 Aug 2020' | (b) (4), (b) (6)       | 11 Aug 2020 16:03:58 |

US3292103

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:20:34

[Is the participant of childbearing potential?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:03:58 |

US3292103

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:20:34

[If No, what is the reason?](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)           | 28 Apr 2021 21:02:25 |
| DataPoint Verified.  | (b) (4), (b) (6)           | 09 Mar 2021 22:07:36 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 22 Feb 2021 18:45:07 |
| User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).             | (b) (4), (b) (6)           | 29 Sep 2020 16:33:03 |
| Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) | 22 Sep 2020 20:58:51 |
| User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).             | (b) (4), (b) (6)           | 27 Aug 2020 04:47:17 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)'   | (b) (4), (b) (6)           | 11 Aug 2020 16:03:58 |

US3292103

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:20:34

If Partner medically sterile or Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:03:58 |

**US3292103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:03:58 |

**US3292103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 16:20:34**

[Date of surgery unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:03:58 |



**US3292103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 09 Mar 2021 22:07:36 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'un UNK 2007' | (b) (4), (b) (6)       | 11 Aug 2020 16:03:58 |

**US3292103**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 16:20:34**

[Date of last menstruation unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:03:58 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |



US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

[Other](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

[Specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

No Risk Identified

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'l'          | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |



US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

[Other](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:20:34

[Specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 21:02:25 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Mar 2021 22:07:46 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:04:23 |

US3292103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:20:34

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:43:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:04:37 |



**US3292103**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 10 Mar 2021 15:43:45 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '08 Aug 2020' | (b) (4), (b) (6)       | 11 Aug 2020 16:04:37 |

US3292103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:20:34

[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 14:20:53 |
| DataPoint Verified.            | (b) (4), (b) (6)       | 10 Mar 2021 15:43:45 |
| User signature succeeded.      | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6)       | 11 Aug 2020 16:04:37 |

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'VISIT1' | System           | 11 Aug 2020 16:04:37 |

US3292103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:20:34

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)                            | 10 Mar 2021 15:45:28 |
| User signature succeeded.  | Douglas Denham (b) (4)                      | 22 Feb 2021 18:45:09 |
| User entered '08 AUG 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 08 Aug 2020 22:15:34 |

US3292103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:20:34

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

| Audit   | User  | Time (GMT)                                   |
|---|---|--|
| Data hard locked.   | (b) (4), (b) (6)                            | 14 Apr 2021 14:20:53                         |
| User closed query 'Per source, Randomization number is 185369. Please review and reconcile. ' (Site from CRA).<br>DataPoint Verified.                       | (b) (4), (b) (6)                            | 05 Apr 2021 20:44:20                         |
| Query 'Per source, Randomization number is 185369. Please review and reconcile. ' answered with 'updated source' (Site from CRA).<br>DataPoint Un-verified. | Dawn Killian (b) (4)<br>(b) (4)             | 23 Mar 2021 18:25:36                         |
| DataPoint Verified.   | (b) (4), (b) (6)                            | 10 Mar 2021 15:45:33                         |
| User opened query 'Per source, Randomization number is 185369. Please review and reconcile. ' (Site from CRA).<br>User signature succeeded.                 | (b) (4), (b) (6)<br>(b) (4), (b) (6)        | 10 Mar 2021 15:45:28<br>10 Mar 2021 15:45:22 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).  | Douglas Denham (b) (4)<br>(b) (4)<br>System | 22 Feb 2021 18:45:09<br>21 Aug 2020 03:10:09 |
| Amendment Manager: Data point set to conformant.  | System                                      | 21 Aug 2020 03:10:08                         |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System).   | System                                      | 08 Aug 2020 22:15:34                         |
| User entered '185367' (non-conformant).   | RWS_ENDPOINT<br>ENDPOINT (b) (4)            | 08 Aug 2020 22:15:34                         |

US3292103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:20:34

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

| Audit                         | User  | Time (GMT)           |
|-------------------------------|---|----------------------|
| Data hard locked.             | (b) (4), (b) (6)                            | 14 Apr 2021 14:20:53 |
| DataPoint Verified.           | (b) (4), (b) (6)                            | 10 Mar 2021 15:45:28 |
| User signature succeeded.     | Douglas Denham (b) (4)                      | 22 Feb 2021 18:45:09 |
| User entered '>=65 years (3)' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 08 Aug 2020 22:15:34 |

US3292103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:20:34

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:45:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:55 |

US3292103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:20:34

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 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:45:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:55 |



**US3292103**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:45:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:55 |

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:20:34**

**Diabetes (Type I, Type 2, or gestational)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:45:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:55 |

US3292103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:20:34

[Liver Disease](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:45:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:04:55 |

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:20:34**

[Height](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)       | 13 Aug 2020 19:43:09 |
| User entered empty.   |                        | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:20:34

Weight

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)       | 13 Aug 2020 19:43:09 |
| User entered empty.   |                        | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:20:34

[Height](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)       | 13 Aug 2020 19:43:09 |
| User entered empty.   | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:20:34

[Weight](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)       | 13 Aug 2020 19:43:09 |
| User entered empty.   | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 11 Aug 2020 16:06:40 |



US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '08 Aug 2020' | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:20:34**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '16:05'      | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered '08 Aug 2020 16:05' | System           | 11 Aug 2020 16:06:40 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '037.0' C    | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Route of measurement](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:20:34**

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Pulse \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '078'        | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |



US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'bpm' | System           | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '012'        | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'breaths/min' | System           | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

Systolic Blood Pressure (xxx)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).         | (b) (4), (b) (6)       | 12 Aug 2020 16:42:30 |
| Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 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)       | 11 Aug 2020 16:07:20 |
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).         | System                 | 11 Aug 2020 16:06:40 |
| User entered '159'  | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'mmHg' | System           | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

Diastolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '081'        | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'mmHg' | System           | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:20:34

[Height](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)       | 13 Aug 2020 19:43:09 |
| User entered empty.   | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |



US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:20:34

[Weight](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)       | 13 Aug 2020 19:43:09 |
| User entered empty.   | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '08 Aug 2020' | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

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

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).   | (b) (4), (b) (6)       | 13 Aug 2020 14:56:31 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'as per protocol post dose vitals can be measured after 30 minutes' (Site from System). | (b) (4), (b) (6)       | 11 Aug 2020 16:07:34 |
| User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).   |                        | 11 Aug 2020 16:06:40 |
| User entered '18:55'   | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered '08 Aug 2020 18:55' | System           | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '037.1' C    | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Route of measurement](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |



**US3292103**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:20:34**

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Pulse \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '084'        | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'bpm' | System           | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '014'        | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'breaths/min' | System           | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

Systolic Blood Pressure (xxx)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 14 Apr 2021 14:20:53 |
| User closed query 'Per progress note, BP was repeated (161/86). please reconcile. ' (Site from CRA).  | (b) (4), (b) (6)                  | 25 Mar 2021 20:09:28 |
| DataPoint Verified.   | (b) (4), (b) (6)                  | 25 Mar 2021 20:09:26 |
| Query 'Per progress note, BP was repeated (161/86). please reconcile. ' answered with 'bp was repeated but this was pre-dose! updated unscheduled event' (Site from CRA).                                   | Dawn Killian (b) (4)<br>(b) (4)   | 23 Mar 2021 18:21:34 |
| User opened query 'Per progress note, BP was repeated (161/86). please reconcile. ' (Site from CRA).  | (b) (4), (b) (6)                  | 10 Mar 2021 15:58:27 |
| DataPoint Un-verified.  | (b) (4), (b) (6)                  | 10 Mar 2021 15:54:41 |
| DataPoint Verified.   | (b) (4), (b) (6)                  | 10 Mar 2021 15:53:28 |
| User signature succeeded.   | Douglas Denham (b) (4)<br>(b) (4) | 22 Feb 2021 18:45:09 |
| User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).         | (b) (4), (b) (6)                  | 17 Aug 2020 16:57:04 |
| Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System). |                                   | 14 Aug 2020 19:54:19 |
| User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).         | System                            | 11 Aug 2020 16:06:40 |
| User entered '157'  | (b) (4), (b) (6)                  | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'mmHg' | System           | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

Diastolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 25 Mar 2021 20:09:32 |
| DataPoint Un-verified.    | (b) (4), (b) (6)       | 10 Mar 2021 15:58:30 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:55:58 |
| DataPoint Un-verified.    | (b) (4), (b) (6)       | 10 Mar 2021 15:54:43 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 15:53:28 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '084'        | (b) (4), (b) (6)       | 11 Aug 2020 16:06:40 |



US3292103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'mmHg' | System           | 11 Aug 2020 16:06:40 |

US3292103

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:20:34

[Was the physical examination performed?](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.                                       | (b) (4), (b) (6)       | 10 Mar 2021 16:00:40 |
| User signature succeeded.                                 | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6)       | 14 Aug 2020 01:25:46 |
| User entered 'Yes (Y)'                                    | (b) (4), (b) (6)       | 11 Aug 2020 16:08:30 |

US3292103

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:20:34

Date of examination (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.                                    | (b) (4), (b) (6)       | 10 Mar 2021 16:00:40 |
| User signature succeeded.                              | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)       | 14 Aug 2020 01:25:46 |
| User entered '08 Aug 2020'                             | (b) (4), (b) (6)       | 11 Aug 2020 16:08:30 |

US3292103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[Was study treatment given?](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                         | 10 Mar 2021 16:01:15 |
| User signature succeeded. | Douglas Denham (b) (4)                   | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>Darlington Akahara<br>(b) (4) | 08 Aug 2020 23:39:00 |

US3292103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[If No, reason not given](#)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                         | 10 Mar 2021 16:01:15 |
| User signature succeeded. | Douglas Denham (b) (4)                   | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4)<br>Darlington Akahara<br>(b) (4) | 08 Aug 2020 23:39:00 |

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

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

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                         | 10 Mar 2021 16:01:15 |
| User signature succeeded. | Douglas Denham (b) (4)                   | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4)<br>Darlington Akahara<br>(b) (4) | 08 Aug 2020 23:39:00 |

US3292103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

What was the treatment date? (dd MMM yyyy)

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                         | 10 Mar 2021 16:01:15 |
| User signature succeeded. | Douglas Denham (b) (4)                   | 22 Feb 2021 18:45:09 |
| User entered '8 Aug 2020' | (b) (4)<br>Darlington Akahara<br>(b) (4) | 08 Aug 2020 23:39:00 |



US3292103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

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

| Audit                     | User                                     | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                         | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                         | 10 Mar 2021 16:01:15 |
| User signature succeeded. | Douglas Denham (b) (4)                   | 22 Feb 2021 18:45:09 |
| User entered '18:22'      | (b) (4)<br>Darlington Akahara<br>(b) (4) | 08 Aug 2020 23:39:00 |

US3292103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[Treatment Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered '8 Aug 2020 18:22' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[Which arm was used to give treatment?](#)

| Audit                              | User                                     | Time (GMT)           |
|------------------------------------|--|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)                         | 14 Apr 2021 14:20:53 |
| DataPoint Verified.                | (b) (4), (b) (6)                         | 10 Mar 2021 16:01:15 |
| User signature succeeded.          | Douglas Denham (b) (4)                   | 22 Feb 2021 18:45:09 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4)<br>Darlington Akahara<br>(b) (4) | 08 Aug 2020 23:39:00 |

US3292103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 16:01:15 |
| User entered 'ONCE' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'INTRAMUSCULAR' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:02:31 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:08:49 |

US3292103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

Collection date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 10 Mar 2021 16:02:31 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '08 Aug 2020' | (b) (4), (b) (6)       | 11 Aug 2020 16:08:49 |

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:20:34**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:02:31 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '16:30'      | (b) (4), (b) (6)       | 11 Aug 2020 16:08:49 |



US3292103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered '08 Aug 2020 16:30' | System           | 11 Aug 2020 16:08:49 |

US3292103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:20:34

Collection date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 10 Mar 2021 16:04:07 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '08 Aug 2020' | (b) (4), (b) (6)       | 11 Aug 2020 16:09:06 |

US3292103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:20:34

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 11 Aug 2020 16:09:06 |

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:04:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:09:06 |

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:20:34**

**Collection time (00:00 - 23:59)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:04:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '16:25'      | (b) (4), (b) (6)       | 11 Aug 2020 16:09:06 |

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered '08 Aug 2020 16:25' | System           | 11 Aug 2020 16:09:06 |

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 11 Aug 2020 16:09:06 |

US3292103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:20:34

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:04:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:09:06 |



**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:20:34**

**Collection time (00:00 - 23:59)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:04:07 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:09:06 |

**US3292103**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered empty. | System           | 11 Aug 2020 16:09:06 |

US3292103

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:20:34

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:04:12 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:09:10 |

US3292103

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:20:34

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'l'  | System           | 11 Aug 2020 16:09:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

TIMEPOINT

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:02', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '85c93d83-83ed-4794-bc95-acd42ca0ab0e' User entered 'Yes (Y)' | System           | 08 Aug 2020 23:55:21 |
|   | System           | 08 Aug 2020 23:55:21 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:08', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '85c93d83-83ed-4794-bc95-acd42ca0ab0e' User entered '98.7' | System           | 08 Aug 2020 23:55:21 |
|  | System           | 08 Aug 2020 23:55:21 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:14', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '85c93d83-83ed-4794-bc95-acd42ca0ab0e' User entered 'No (N)' | System           | 08 Aug 2020 23:55:21 |
|  | System           | 08 Aug 2020 23:55:21 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '85c93d83-83ed-4794-bc95-acd42ca0ab0e' User entered '08 Aug 2020 18:55' | System           | 08 Aug 2020 23:55:21 |
|   | System           | 08 Aug 2020 23:55:21 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Aug 2020 18:42' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Aug 2020 21:12' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.                                | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 1, after vaccination (at home)' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:08:13', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10ce8aeb-0a7e-47d7-bcc8-db930badb461' User entered 'Yes (Y)' | System           | 09 Aug 2020 03:08:53 |
|   | System           | 09 Aug 2020 03:08:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:08:23', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10ce8aeb-0a7e-47d7-bcc8-db930badb461' User entered '97.3' | System           | 09 Aug 2020 03:08:53 |
|  | System           | 09 Aug 2020 03:08:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:08:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10ce8aeb-0a7e-47d7-bcc8-db930badb461' User entered 'Yes (Y)' | System           | 09 Aug 2020 03:08:53 |
|   | System           | 09 Aug 2020 03:08:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4), (b) (6)           | 28 Sep 2020 15:37:07 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication documented' (Site from System).  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:38:05 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).  | System                     | 09 Aug 2020 03:08:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:08:49', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10ce8aeb-0a7e-47d7-bcc8-db930badb461'  | System                     | 09 Aug 2020 03:08:53 |
| User entered '1'  | System                     | 09 Aug 2020 03:08:53 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:08:49', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10ce8aeb-0a7e-47d7-bcc8-db930badb461' User entered '0' | System           | 09 Aug 2020 03:08:53 |
|   | System           | 09 Aug 2020 03:08:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:08:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10ce8aeb-0a7e-47d7-bcc8-db930badb461' User entered '08 Aug 2020 22:08' | System           | 09 Aug 2020 03:08:53 |
|   | System           | 09 Aug 2020 03:08:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Aug 2020 22:07' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '09 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 2' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:04', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '86527897-d01c-4da0-b461-dffedb5b1666' | System           | 09 Aug 2020 23:01:39 |
| User entered 'Yes (Y)'   | System           | 09 Aug 2020 23:01:39 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '86527897-d01c-4da0-b461-dffedb5b1666' User entered '98.2' | System           | 09 Aug 2020 23:01:39 |
|  | System           | 09 Aug 2020 23:01:39 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:16', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '86527897-d01c-4da0-b461-dffedb5b1666' | System           | 09 Aug 2020 23:01:39 |
| User entered 'Yes (Y)'   | System           | 09 Aug 2020 23:01:39 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4)                    | 28 Sep 2020 15:37:15 |
| 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).  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:38:42 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '86527897-d01c-4da0-b461-dffedb5b1666'  | System                     | 09 Aug 2020 23:01:39 |
| User entered 'I'  | System                     | 09 Aug 2020 23:01:39 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '86527897-d01c-4da0-b461-dffedb5b1666' User entered '0' | System           | 09 Aug 2020 23:01:39 |
|   | System           | 09 Aug 2020 23:01:39 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:37', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '86527897-d01c-4da0-b461-dffedb5b1666' User entered '09 Aug 2020 18:01' | System           | 09 Aug 2020 23:01:39 |
|   | System           | 09 Aug 2020 23:01:39 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '09 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '10 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 3' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:28:13', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9a6eaaf2-cbe8-4e6c-ab43-75384ac8d27f' User entered 'Yes (Y)' | System           | 10 Aug 2020 23:28:54 |
|   | System           | 10 Aug 2020 23:28:54 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:28:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9a6eaaf2-cbe8-4e6c-ab43-75384ac8d27f' User entered '98.0' | System           | 10 Aug 2020 23:28:54 |
|  | System           | 10 Aug 2020 23:28:54 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:28:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9a6eaaf2-cbe8-4e6c-ab43-75384ac8d27f' User entered 'Yes (Y)' | System           | 10 Aug 2020 23:28:54 |
|   | System           | 10 Aug 2020 23:28:54 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4)                    | 28 Sep 2020 15:37:21 |
| 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).  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:39:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:28:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9a6eaaf2-cbe8-4e6c-ab43-75384ac8d27f'  | System                     | 10 Aug 2020 23:28:54 |
| User entered '1'  | System                     | 10 Aug 2020 23:28:54 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:28:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9a6eaaf2-cbe8-4e6c-ab43-75384ac8d27f' User entered '0' | System           | 10 Aug 2020 23:28:54 |
|   | System           | 10 Aug 2020 23:28:54 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:28:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9a6eaaf2-cbe8-4e6c-ab43-75384ac8d27f' User entered '10 Aug 2020 18:28' | System           | 10 Aug 2020 23:28:54 |
|   | System           | 10 Aug 2020 23:28:54 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '10 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '11 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 4' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '90442d75-8bd9-4940-8352-5e62a6ac8d90' | System           | 11 Aug 2020 21:57:48 |
| User entered 'Yes (Y)'   | System           | 11 Aug 2020 21:57:48 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '90442d75-8bd9-4940-8352-5e62a6ac8d90' | System           | 11 Aug 2020 21:57:48 |
| User entered '97.8'  | System           | 11 Aug 2020 21:57:48 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '90442d75-8bd9-4940-8352-5e62a6ac8d90' | System           | 11 Aug 2020 21:57:48 |
| User entered 'Yes (Y)'   | System           | 11 Aug 2020 21:57:48 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4)                    | 28 Sep 2020 15:37:27 |
| 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).  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:39:32 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '90442d75-8bd9-4940-8352-5e62a6ac8d90'  | System                     | 11 Aug 2020 21:57:48 |
| User entered '1'  | System                     | 11 Aug 2020 21:57:48 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '90442d75-8bd9-4940-8352-5e62a6ac8d90' | System           | 11 Aug 2020 21:57:48 |
| User entered '0'   | System           | 11 Aug 2020 21:57:48 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '90442d75-8bd9-4940-8352-5e62a6ac8d90' | System           | 11 Aug 2020 21:57:48 |
| User entered '11 Aug 2020 16:57'   | System           | 11 Aug 2020 21:57:48 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '11 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '12 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 5' | System           | 08 Aug 2020 23:39:00 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:33:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '36aac65-24d6-4805-8244-ad16ee9944d7' User entered 'Yes (Y)' | System           | 12 Aug 2020 22:33:55 |
|  | System           | 12 Aug 2020 22:33:55 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:33:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '36aac65-24d6-4805-8244-ad16ee9944d7' User entered '98.2' | System           | 12 Aug 2020 22:33:55 |
|   | System           | 12 Aug 2020 22:33:55 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:33:29', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '36aac65-24d6-4805-8244-ad16ee9944d7' | System           | 12 Aug 2020 22:33:55 |
| User entered 'Yes (Y)'  | System           | 12 Aug 2020 22:33:55 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4)                    | 28 Sep 2020 15:37:33 |
| 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).  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:39:57 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:33:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '36aac65-24d6-4805-8244-ad16ee9944d7'   | System                     | 12 Aug 2020 22:33:55 |
| User entered '1'  | System                     | 12 Aug 2020 22:33:55 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:33:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '36aac65-24d6-4805-8244-ad16ee9944d7' User entered '0' | System           | 12 Aug 2020 22:33:55 |
|  | System           | 12 Aug 2020 22:33:55 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:33:51', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '36aac65-24d6-4805-8244-ad16ee9944d7' User entered '12 Aug 2020 17:33' | System           | 12 Aug 2020 22:33:55 |
|  | System           | 12 Aug 2020 22:33:55 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '12 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '13 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 6' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:23:42', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9f7a7663-cd38-48cb-8d57-f5f68b56981c' User entered 'Yes (Y)' | System           | 13 Aug 2020 22:24:14 |
|   | System           | 13 Aug 2020 22:24:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:23:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9f7a7663-cd38-48cb-8d57-f5f68b56981c' User entered '98.0' | System           | 13 Aug 2020 22:24:14 |
|  | System           | 13 Aug 2020 22:24:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:23:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9f7a7663-cd38-48cb-8d57-f5f68b56981c' | System           | 13 Aug 2020 22:24:14 |
| User entered 'Yes (Y)'   | System           | 13 Aug 2020 22:24:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4)                    | 28 Sep 2020 15:37:39 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:40:19 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9f7a7663-cd38-48cb-8d57-f5f68b56981c'  | System                     | 13 Aug 2020 22:24:14 |
| User entered '1'  | System                     | 13 Aug 2020 22:24:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9f7a7663-cd38-48cb-8d57-f5f68b56981c' User entered '0' | System           | 13 Aug 2020 22:24:14 |
|   | System           | 13 Aug 2020 22:24:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9f7a7663-cd38-48cb-8d57-f5f68b56981c' User entered '13 Aug 2020 17:24' | System           | 13 Aug 2020 22:24:14 |
|   | System           | 13 Aug 2020 22:24:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '13 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '14 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 7' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:50:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c7ee065a-c3d9-40fc-91d5-b4a26e906b7b' User entered 'Yes (Y)' | System           | 14 Aug 2020 21:51:11 |
|   | System           | 14 Aug 2020 21:51:11 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:50:49', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c7ee065a-c3d9-40fc-91d5-b4a26e906b7b' User entered '98.0' | System           | 14 Aug 2020 21:51:11 |
|  | System           | 14 Aug 2020 21:51:11 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:50:54', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c7ee065a-c3d9-40fc-91d5-b4a26e906b7b' User entered 'Yes (Y)' | System           | 14 Aug 2020 21:51:11 |
|   | System           | 14 Aug 2020 21:51:11 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4)                    | 28 Sep 2020 15:37:45 |
| 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).  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:41:17 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c7ee065a-c3d9-40fc-91d5-b4a26e906b7b'  | System                     | 14 Aug 2020 21:51:11 |
| User entered '1'  | System                     | 14 Aug 2020 21:51:11 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c7ee065a-c3d9-40fc-91d5-b4a26e906b7b' User entered '0' | System           | 14 Aug 2020 21:51:11 |
|   | System           | 14 Aug 2020 21:51:11 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c7ee065a-c3d9-40fc-91d5-b4a26e906b7b' User entered '14 Aug 2020 16:51' | System           | 14 Aug 2020 21:51:11 |
|   | System           | 14 Aug 2020 21:51:11 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '14 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '15 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 13 Aug 2020 22:24:14 |
| User entered 'Day 8' | System           | 13 Aug 2020 22:24:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:02', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e61d320d-9a1e-4126-ba05-ab9b9a7d04ac' User entered 'Yes (Y)' | System           | 15 Aug 2020 20:58:29 |
|   | System           | 15 Aug 2020 20:58:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e61d320d-9a1e-4126-ba05-ab9b9a7d04ac' User entered '97.8' | System           | 15 Aug 2020 20:58:29 |
|  | System           | 15 Aug 2020 20:58:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:11', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e61d320d-9a1e-4126-ba05-ab9b9a7d04ac' | System           | 15 Aug 2020 20:58:29 |
| User entered 'Yes (Y)'   | System           | 15 Aug 2020 20:58:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4)                    | 28 Sep 2020 15:37:52 |
| 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).  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:41:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e61d320d-9a1e-4126-ba05-ab9b9a7d04ac'  | System                     | 15 Aug 2020 20:58:29 |
| User entered '1'  | System                     | 15 Aug 2020 20:58:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e61d320d-9a1e-4126-ba05-ab9b9a7d04ac' User entered '0' | System           | 15 Aug 2020 20:58:29 |
|   | System           | 15 Aug 2020 20:58:29 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e61d320d-9a1e-4126-ba05-ab9b9a7d04ac' | System           | 15 Aug 2020 20:58:29 |
| User entered '15 Aug 2020 15:58'   | System           | 15 Aug 2020 20:58:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '15 Aug 2020 12:00' | System           | 13 Aug 2020 22:24:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '16 Aug 2020 11:59' | System           | 13 Aug 2020 22:24:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 14 Aug 2020 21:51:11 |
| User entered 'Day 9' | System           | 14 Aug 2020 21:51:11 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:16', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'de3fe81b-073a-4580-b016-83b59353787a' User entered 'Yes (Y)' | System           | 16 Aug 2020 20:16:46 |
|   | System           | 16 Aug 2020 20:16:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:23', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'de3fe81b-073a-4580-b016-83b59353787a' User entered '96.8' | System           | 16 Aug 2020 20:16:46 |
|  | System           | 16 Aug 2020 20:16:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:27', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'de3fe81b-073a-4580-b016-83b59353787a' User entered 'Yes (Y)' | System           | 16 Aug 2020 20:16:46 |
|   | System           | 16 Aug 2020 20:16:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4)                    | 28 Sep 2020 15:37:57 |
| 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).  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:42:48 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'de3fe81b-073a-4580-b016-83b59353787a'  | System                     | 16 Aug 2020 20:16:46 |
| User entered '1'  | System                     | 16 Aug 2020 20:16:46 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'de3fe81b-073a-4580-b016-83b59353787a' User entered '0' | System           | 16 Aug 2020 20:16:46 |
|   | System           | 16 Aug 2020 20:16:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:42', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'de3fe81b-073a-4580-b016-83b59353787a' User entered '16 Aug 2020 15:16' | System           | 16 Aug 2020 20:16:46 |
|   | System           | 16 Aug 2020 20:16:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '16 Aug 2020 12:00' | System           | 14 Aug 2020 21:51:11 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '17 Aug 2020 11:59' | System           | 14 Aug 2020 21:51:11 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 15 Aug 2020 20:58:29 |
| User entered 'Day 10' | System           | 15 Aug 2020 20:58:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:04', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '646e03b7-d423-4710-a5b7-22469d42e5e1' User entered 'Yes (Y)' | System           | 17 Aug 2020 19:18:29 |
|   | System           | 17 Aug 2020 19:18:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '646e03b7-d423-4710-a5b7-22469d42e5e1' User entered '97.7' | System           | 17 Aug 2020 19:18:29 |
|  | System           | 17 Aug 2020 19:18:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:13', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '646e03b7-d423-4710-a5b7-22469d42e5e1' User entered 'Yes (Y)' | System           | 17 Aug 2020 19:18:29 |
|   | System           | 17 Aug 2020 19:18:29 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4)                    | 28 Sep 2020 15:38:05 |
| 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).  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:43:13 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '646e03b7-d423-4710-a5b7-22469d42e5e1'  | System                     | 17 Aug 2020 19:18:29 |
| User entered 'I'  | System                     | 17 Aug 2020 19:18:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '646e03b7-d423-4710-a5b7-22469d42e5e1' User entered '0' | System           | 17 Aug 2020 19:18:29 |
|   | System           | 17 Aug 2020 19:18:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '646e03b7-d423-4710-a5b7-22469d42e5e1' User entered '17 Aug 2020 14:18' | System           | 17 Aug 2020 19:18:29 |
|   | System           | 17 Aug 2020 19:18:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '17 Aug 2020 12:00' | System           | 15 Aug 2020 20:58:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '18 Aug 2020 11:59' | System           | 15 Aug 2020 20:58:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 16 Aug 2020 20:16:46 |
| User entered 'Day 11' | System           | 16 Aug 2020 20:16:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:03', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'caaec2f6-c780-4ad3-86a8-08ee88f0eaf7' | System           | 18 Aug 2020 21:07:24 |
| User entered 'Yes (Y)'   | System           | 18 Aug 2020 21:07:24 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'caaec2f6-c780-4ad3-86a8-08ee88f0eaf7' User entered '98.2' | System           | 18 Aug 2020 21:07:24 |
|  | System           | 18 Aug 2020 21:07:24 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'caaec2f6-c780-4ad3-86a8-08ee88f0eaf7' | System           | 18 Aug 2020 21:07:24 |
| User entered 'Yes (Y)'   | System           | 18 Aug 2020 21:07:24 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4)                    | 28 Sep 2020 15:38:12 |
| 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).  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:43:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'caaec2f6-c780-4ad3-86a8-08ee88f0eaf7'  | System                     | 18 Aug 2020 21:07:24 |
| User entered '1'  | System                     | 18 Aug 2020 21:07:24 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'caaec2f6-c780-4ad3-86a8-08ee88f0eaf7' User entered '0' | System           | 18 Aug 2020 21:07:24 |
|   | System           | 18 Aug 2020 21:07:24 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:22', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'caaec2f6-c780-4ad3-86a8-08ee88f0eaf7' User entered '18 Aug 2020 16:07' | System           | 18 Aug 2020 21:07:24 |
|   | System           | 18 Aug 2020 21:07:24 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '18 Aug 2020 12:00' | System           | 16 Aug 2020 20:16:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '19 Aug 2020 11:59' | System           | 16 Aug 2020 20:16:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 17 Aug 2020 19:18:29 |
| User entered 'Day 12' | System           | 17 Aug 2020 19:18:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '483186a3-ab3c-434e-a9f6-6bad6f169481' User entered 'Yes (Y)' | System           | 19 Aug 2020 23:17:53 |
|   | System           | 19 Aug 2020 23:17:53 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '483186a3-ab3c-434e-a9f6-6bad6f169481' User entered '98.2' | System           | 19 Aug 2020 23:17:53 |
|  | System           | 19 Aug 2020 23:17:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:42', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '483186a3-ab3c-434e-a9f6-6bad6f169481' | System           | 19 Aug 2020 23:17:53 |
| User entered 'Yes (Y)'   | System           | 19 Aug 2020 23:17:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4), (b) (6)           | 28 Sep 2020 15:38:17 |
| 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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '483186a3-ab3c-434e-a9f6-6bad6f169481' User entered '1'          | Victoria Hernandez (b) (4) | 17 Sep 2020 16:44:07 |
| 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                     | 19 Aug 2020 23:17:53 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '483186a3-ab3c-434e-a9f6-6bad6f169481' User entered '1'   | System                     | 19 Aug 2020 23:17:53 |
| User entered '1'  | System                     | 19 Aug 2020 23:17:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '483186a3-ab3c-434e-a9f6-6bad6f169481' User entered '0' | System           | 19 Aug 2020 23:17:53 |
|   | System           | 19 Aug 2020 23:17:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '483186a3-ab3c-434e-a9f6-6bad6f169481' | System           | 19 Aug 2020 23:17:53 |
| User entered '19 Aug 2020 18:17'   | System           | 19 Aug 2020 23:17:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '19 Aug 2020 12:00' | System           | 17 Aug 2020 19:18:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '20 Aug 2020 11:59' | System           | 17 Aug 2020 19:18:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 18 Aug 2020 21:07:24 |
| User entered 'Day 13' | System           | 18 Aug 2020 21:07:24 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:18', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '62a303d0-20a4-4b02-812b-1b6a6a422a30' User entered 'Yes (Y)' | System           | 20 Aug 2020 20:24:42 |
|   | System           | 20 Aug 2020 20:24:42 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '62a303d0-20a4-4b02-812b-1b6a6a422a30' User entered '98.0' | System           | 20 Aug 2020 20:24:42 |
|  | System           | 20 Aug 2020 20:24:42 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '62a303d0-20a4-4b02-812b-1b6a6a422a30' User entered 'Yes (Y)' | System           | 20 Aug 2020 20:24:42 |
|   | System           | 20 Aug 2020 20:24:42 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4)                    | 28 Sep 2020 15:38:22 |
| 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).  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:44:31 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:34', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '62a303d0-20a4-4b02-812b-1b6a6a422a30'  | System                     | 20 Aug 2020 20:24:42 |
| User entered '1'  | System                     | 20 Aug 2020 20:24:42 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:34', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '62a303d0-20a4-4b02-812b-1b6a6a422a30' User entered '0' | System           | 20 Aug 2020 20:24:42 |
|   | System           | 20 Aug 2020 20:24:42 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:37', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '62a303d0-20a4-4b02-812b-1b6a6a422a30' User entered '20 Aug 2020 15:24' | System           | 20 Aug 2020 20:24:42 |
|   | System           | 20 Aug 2020 20:24:42 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '20 Aug 2020 12:00' | System           | 18 Aug 2020 21:07:24 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '21 Aug 2020 11:59' | System           | 18 Aug 2020 21:07:24 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 19 Aug 2020 23:17:53 |
| User entered 'Day 14' | System           | 19 Aug 2020 23:17:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '163b76c2-9c7d-4903-b68a-0735e4e21ede' User entered 'Yes (Y)' | System           | 22 Aug 2020 04:59:53 |
|   | System           | 22 Aug 2020 04:59:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:39', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '163b76c2-9c7d-4903-b68a-0735e4e21ede' User entered '98.2' | System           | 22 Aug 2020 04:59:53 |
|  | System           | 22 Aug 2020 04:59:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '163b76c2-9c7d-4903-b68a-0735e4e21ede' User entered 'Yes (Y)' | System           | 22 Aug 2020 04:59:53 |
|   | System           | 22 Aug 2020 04:59:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4)                    | 28 Sep 2020 15:38:28 |
| 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).  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:44:56 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '163b76c2-9c7d-4903-b68a-0735e4e21ede'  | System                     | 22 Aug 2020 04:59:53 |
| User entered '1'  | System                     | 22 Aug 2020 04:59:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '163b76c2-9c7d-4903-b68a-0735e4e21ede' User entered '0' | System           | 22 Aug 2020 04:59:53 |
|   | System           | 22 Aug 2020 04:59:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:51', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '163b76c2-9c7d-4903-b68a-0735e4e21ede' User entered '21 Aug 2020 23:59' | System           | 22 Aug 2020 04:59:53 |
|   | System           | 22 Aug 2020 04:59:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '21 Aug 2020 12:00' | System           | 19 Aug 2020 23:17:53 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '22 Aug 2020 11:59' | System           | 19 Aug 2020 23:17:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 20 Aug 2020 20:24:42 |
| User entered 'Day 15' | System           | 20 Aug 2020 20:24:42 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '05a8f84d-8ca9-4c96-835e-868e6fe23626' User entered 'Yes (Y)' | System           | 22 Aug 2020 22:12:40 |
|   | System           | 22 Aug 2020 22:12:40 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '05a8f84d-8ca9-4c96-835e-868e6fe23626' User entered '98.0' | System           | 22 Aug 2020 22:12:40 |
|  | System           | 22 Aug 2020 22:12:40 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '05a8f84d-8ca9-4c96-835e-868e6fe23626' | System           | 22 Aug 2020 22:12:40 |
| User entered 'Yes (Y)'   | System           | 22 Aug 2020 22:12:40 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4)                    | 28 Sep 2020 15:38:36 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '05a8f84d-8ca9-4c96-835e-868e6fe23626'                           | Victoria Hernandez (b) (4) | 17 Sep 2020 16:45:25 |
| User entered '1'  | System                     | 22 Aug 2020 22:12:40 |
|   | System                     | 22 Aug 2020 22:12:40 |
|   | System                     | 22 Aug 2020 22:12:40 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '05a8f84d-8ca9-4c96-835e-868e6fe23626' User entered '0' | System           | 22 Aug 2020 22:12:40 |
|   | System           | 22 Aug 2020 22:12:40 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '05a8f84d-8ca9-4c96-835e-868e6fe23626' User entered '22 Aug 2020 17:12' | System           | 22 Aug 2020 22:12:40 |
|   | System           | 22 Aug 2020 22:12:40 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '22 Aug 2020 12:00' | System           | 20 Aug 2020 20:24:42 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '23 Aug 2020 11:59' | System           | 20 Aug 2020 20:24:42 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 22 Aug 2020 04:59:53 |
| User entered 'Day 16' | System           | 22 Aug 2020 04:59:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:06:46', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a45bcff7-d86c-4a14-8841-bda1d6d90998' | System           | 23 Aug 2020 21:07:05 |
| User entered 'Yes (Y)'   | System           | 23 Aug 2020 21:07:05 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:06:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a45bcff7-d86c-4a14-8841-bda1d6d90998' User entered '97.5' | System           | 23 Aug 2020 21:07:05 |
|  | System           | 23 Aug 2020 21:07:05 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:06:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a45bcff7-d86c-4a14-8841-bda1d6d90998' | System           | 23 Aug 2020 21:07:05 |
| User entered 'Yes (Y)'   | System           | 23 Aug 2020 21:07:05 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 09 Jun 2021 16:20:34

To **TREAT** pain or fever that has already occurred

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 04 Mar 2021 23:51:25 |
| 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 documented' (Site from System). | (b) (4), (b) (6)           | 28 Sep 2020 15:38:41 |
| 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 (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:06:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a45bcff7-d86c-4a14-8841-bda1d6d90998' User entered '1'          | Victoria Hernandez (b) (4) | 17 Sep 2020 16:46:01 |
|   | System                     | 23 Aug 2020 21:07:05 |
|   | System                     | 23 Aug 2020 21:07:05 |
|   | System                     | 23 Aug 2020 21:07:05 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 09 Jun 2021 16:20:34

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:06:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a45bcff7-d86c-4a14-8841-bda1d6d90998' User entered '0' | System           | 23 Aug 2020 21:07:05 |
|   | System           | 23 Aug 2020 21:07:05 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:07:01', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a45bcff7-d86c-4a14-8841-bda1d6d90998' | System           | 23 Aug 2020 21:07:05 |
| User entered '23 Aug 2020 16:07'   | System           | 23 Aug 2020 21:07:05 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '23 Aug 2020 12:00' | System           | 22 Aug 2020 04:59:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(16)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '24 Aug 2020 11:59' | System           | 22 Aug 2020 04:59:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 22 Aug 2020 22:12:40 |
| User entered 'Day 17' | System           | 22 Aug 2020 22:12:40 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-24T14:54:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '18cd1812-9248-4281-9152-6b92c0db554a' User entered 'Yes (Y)' | System           | 24 Aug 2020 19:54:36 |
|   | System           | 24 Aug 2020 19:54:36 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-24T14:54:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '18cd1812-9248-4281-9152-6b92c0db554a' User entered '97.5' | System           | 24 Aug 2020 19:54:36 |
|  | System           | 24 Aug 2020 19:54:36 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-24T14:54:27', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '18cd1812-9248-4281-9152-6b92c0db554a' | System           | 24 Aug 2020 19:54:36 |
| User entered 'No (N)'  | System           | 24 Aug 2020 19:54:36 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-24T14:54:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '18cd1812-9248-4281-9152-6b92c0db554a' User entered '24 Aug 2020 14:54' | System           | 24 Aug 2020 19:54:36 |
|   | System           | 24 Aug 2020 19:54:36 |



US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '24 Aug 2020 12:00' | System           | 22 Aug 2020 22:12:40 |

US3292103

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(17)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '25 Aug 2020 11:59' | System           | 22 Aug 2020 22:12:40 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1f075399-396e-4a81-b25c-6b180fb9affb' | System           | 08 Aug 2020 23:55:40 |
| User entered 'None (1)'  | System           | 08 Aug 2020 23:55:40 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:29', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1f075399-396c-4a81-b25c-6b180fb9affb' | System           | 08 Aug 2020 23:55:40 |
| User entered 'No (N)'  | System           | 08 Aug 2020 23:55:40 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1f075399-396e-4a81-b25c-6b180fb9affb' | System           | 08 Aug 2020 23:55:40 |
| User entered 'No (N)'  | System           | 08 Aug 2020 23:55:40 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1f075399-396e-4a81-b25c-6b180fb9affb' | System           | 08 Aug 2020 23:55:40 |
| User entered 'None (1)'  | System           | 08 Aug 2020 23:55:40 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1f075399-396e-4a81-b25c-6b180fb9affb' User entered '08 Aug 2020 18:55' | System           | 08 Aug 2020 23:55:40 |
|   | System           | 08 Aug 2020 23:55:40 |



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Aug 2020 18:42' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Aug 2020 21:12' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.                                | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 1, after vaccination (at home)' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:01', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b976b5f3-828b-4f82-b925-99a6cd823239' | System           | 09 Aug 2020 03:09:44 |
| User entered 'Does not interfere with activity (2)'  | System           | 09 Aug 2020 03:09:44 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:24', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b976b5f3-828b-4f82-b925-99a6cd823239' User entered 'No (N)' | System           | 09 Aug 2020 03:09:44 |
|  | System           | 09 Aug 2020 03:09:44 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b976b5f3-828b-4f82-b925-99a6cd823239' User entered 'No (N)' | System           | 09 Aug 2020 03:09:44 |
|  | System           | 09 Aug 2020 03:09:44 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b976b5f3-828b-4f82-b925-99a6cd823239' | System           | 09 Aug 2020 03:09:44 |
| User entered 'None (1)'  | System           | 09 Aug 2020 03:09:44 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b976b5f3-828b-4f82-b925-99a6cd823239' User entered '08 Aug 2020 22:09' | System           | 09 Aug 2020 03:09:44 |
|   | System           | 09 Aug 2020 03:09:44 |



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Aug 2020 22:07' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '09 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 2' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:51', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ce3ad959-defa-4917-83a9-374a358c6105' | System           | 09 Aug 2020 23:02:14 |
| User entered 'Does not interfere with activity (2)'  | System           | 09 Aug 2020 23:02:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:54', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ce3ad959-defa-4917-83a9-374a358c6105' | System           | 09 Aug 2020 23:02:14 |
| User entered 'No (N)'  | System           | 09 Aug 2020 23:02:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:01:57', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ce3ad959-defa-4917-83a9-374a358c6105' | System           | 09 Aug 2020 23:02:14 |
| User entered 'No (N)'  | System           | 09 Aug 2020 23:02:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:03', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ce3ad959-defa-4917-83a9-374a358c6105' | System           | 09 Aug 2020 23:02:14 |
| User entered 'None (1)'  | System           | 09 Aug 2020 23:02:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:13', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ce3ad959-defa-4917-83a9-374a358c6105' User entered '09 Aug 2020 18:02' | System           | 09 Aug 2020 23:02:14 |
|   | System           | 09 Aug 2020 23:02:14 |



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '09 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '10 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 3' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '24272b2e-4d7e-47a9-ad5c-401a57cdbel1a' | System           | 10 Aug 2020 23:29:46 |
| User entered 'Does not interfere with activity (2)'   | System           | 10 Aug 2020 23:29:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '24272b2e-4d7e-47a9-ad5c-401a57cdbc1a' User entered 'No (N)' | System           | 10 Aug 2020 23:29:46 |
|  | System           | 10 Aug 2020 23:29:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:27', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '24272b2e-4d7e-47a9-ad5c-401a57cdbc1a' User entered 'No (N)' | System           | 10 Aug 2020 23:29:46 |
|  | System           | 10 Aug 2020 23:29:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:34', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '24272b2e-4d7e-47a9-ad5c-401a57cdbc1a' User entered 'None (1)' | System           | 10 Aug 2020 23:29:46 |
|  | System           | 10 Aug 2020 23:29:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '24272b2e-4d7e-47a9-ad5c-401a57cdbc1a' User entered '10 Aug 2020 18:29' | System           | 10 Aug 2020 23:29:46 |
|   | System           | 10 Aug 2020 23:29:46 |



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '10 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '11 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 4' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '45fla826-f479-4739-8e51-bed763370c9a' User entered 'None (1)' | System           | 11 Aug 2020 21:58:13 |
|  | System           | 11 Aug 2020 21:58:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:55', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '45f1a826-f479-4739-8e51-bed763370c9a' User entered 'No (N)' | System           | 11 Aug 2020 21:58:13 |
|  | System           | 11 Aug 2020 21:58:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:57:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '45f1a826-f479-4739-8e51-bed763370c9a' | System           | 11 Aug 2020 21:58:13 |
| User entered 'No (N)'  | System           | 11 Aug 2020 21:58:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:01', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '45fla826-f479-4739-8e51-bed763370c9a' User entered 'None (1)' | System           | 11 Aug 2020 21:58:13 |
|  | System           | 11 Aug 2020 21:58:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:11', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '45f1a826-f479-4739-8e51-bed763370c9a' | System           | 11 Aug 2020 21:58:13 |
| User entered '11 Aug 2020 16:58'   | System           | 11 Aug 2020 21:58:13 |



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '11 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '12 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 5' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:06', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b49ac9e3-964f-4995-8285-9c3e24983779' | System           | 12 Aug 2020 22:34:30 |
| User entered 'Does not interfere with activity (2)'  | System           | 12 Aug 2020 22:34:30 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b49ac9e3-964f-4995-8285-9c3e24983779' User entered 'No (N)' | System           | 12 Aug 2020 22:34:30 |
|  | System           | 12 Aug 2020 22:34:30 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b49ac9e3-964f-4995-8285-9c3e24983779' | System           | 12 Aug 2020 22:34:30 |
| User entered 'No (N)'  | System           | 12 Aug 2020 22:34:30 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b49ac9e3-964f-4995-8285-9c3e24983779' | System           | 12 Aug 2020 22:34:30 |
| User entered 'None (1)'  | System           | 12 Aug 2020 22:34:30 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b49ac9e3-964f-4995-8285-9c3e24983779' User entered '12 Aug 2020 17:34' | System           | 12 Aug 2020 22:34:30 |
|   | System           | 12 Aug 2020 22:34:30 |



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '12 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '13 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 6' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0cbe2d1e-de5c-4ed2-9093-bff0bbaeb8ac' | System           | 13 Aug 2020 22:24:35 |
| User entered 'Does not interfere with activity (2)'  | System           | 13 Aug 2020 22:24:35 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:23', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0cbe2d1e-de5c-4ed2-9093-bff0bbaeb8ac' | System           | 13 Aug 2020 22:24:35 |
| User entered 'No (N)'  | System           | 13 Aug 2020 22:24:35 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0cbe2d1e-de5c-4ed2-9093-bff0bbaeb8ac' | System           | 13 Aug 2020 22:24:35 |
| User entered 'No (N)'  | System           | 13 Aug 2020 22:24:35 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:29', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0cbe2d1e-de5c-4ed2-9093-bff0bbaeb8ac' | System           | 13 Aug 2020 22:24:35 |
| User entered 'None (1)'  | System           | 13 Aug 2020 22:24:35 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0cbe2d1e-de5c-4ed2-9093-bff0bbaeb8ac' User entered '13 Aug 2020 17:24' | System           | 13 Aug 2020 22:24:35 |
|   | System           | 13 Aug 2020 22:24:35 |



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '13 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '14 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 7' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:14', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933035ac-ac0b-418b-8eba-03078a638ab6' User entered 'None (1)' | System           | 14 Aug 2020 21:51:35 |
|  | System           | 14 Aug 2020 21:51:35 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:18', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933035ac-ac0b-418b-8eba-03078a638ab6' User entered 'No (N)' | System           | 14 Aug 2020 21:51:35 |
|  | System           | 14 Aug 2020 21:51:35 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:22', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933035ac-ac0b-418b-8eba-03078a638ab6' User entered 'No (N)' | System           | 14 Aug 2020 21:51:35 |
|  | System           | 14 Aug 2020 21:51:35 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933035ac-ac0b-418b-8eba-03078a638ab6' User entered 'None (1)' | System           | 14 Aug 2020 21:51:35 |
|  | System           | 14 Aug 2020 21:51:35 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933035ac-ac0b-418b-8eba-03078a638ab6' User entered '14 Aug 2020 16:51' | System           | 14 Aug 2020 21:51:35 |
|   | System           | 14 Aug 2020 21:51:35 |



US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '14 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '15 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:42', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f' User entered 'None (0)' | System           | 08 Aug 2020 23:56:10 |
|  | System           | 08 Aug 2020 23:56:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f' User entered 'None (0)' | System           | 08 Aug 2020 23:56:10 |
|  | System           | 08 Aug 2020 23:56:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f' User entered 'None (0)' | System           | 08 Aug 2020 23:56:10 |
|  | System           | 08 Aug 2020 23:56:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f' User entered 'None (0)' | System           | 08 Aug 2020 23:56:10 |
|  | System           | 08 Aug 2020 23:56:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f' User entered 'None (0)' | System           | 08 Aug 2020 23:56:10 |
|  | System           | 08 Aug 2020 23:56:10 |



US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

CHILLS

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:55:54', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f' User entered 'None (0)' | System           | 08 Aug 2020 23:56:10 |
|  | System           | 08 Aug 2020 23:56:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:56:04', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f' User entered 'No (N)' | System           | 08 Aug 2020 23:56:10 |
|  | System           | 08 Aug 2020 23:56:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T18:56:08', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bb027e5-1bb4-4b6a-abfc-921889c1d06f' User entered '08 Aug 2020 18:56' | System           | 08 Aug 2020 23:56:10 |
|   | System           | 08 Aug 2020 23:56:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Aug 2020 18:42' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Aug 2020 21:12' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.                                | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 1, after vaccination (at home)' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101' User entered 'None (0)' | System           | 09 Aug 2020 03:10:10 |
|  | System           | 09 Aug 2020 03:10:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101' User entered 'None (0)' | System           | 09 Aug 2020 03:10:10 |
|  | System           | 09 Aug 2020 03:10:10 |



US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101' User entered 'None (0)' | System           | 09 Aug 2020 03:10:10 |
|  | System           | 09 Aug 2020 03:10:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:56', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101' User entered 'None (0)' | System           | 09 Aug 2020 03:10:10 |
|  | System           | 09 Aug 2020 03:10:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:09:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101' User entered 'None (0)' | System           | 09 Aug 2020 03:10:10 |
|  | System           | 09 Aug 2020 03:10:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:10:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101' User entered 'None (0)' | System           | 09 Aug 2020 03:10:10 |
|  | System           | 09 Aug 2020 03:10:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:10:04', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101' User entered 'No (N)' | System           | 09 Aug 2020 03:10:10 |
|  | System           | 09 Aug 2020 03:10:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-08T22:10:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd74306c0-8692-4d17-ab23-6bcb82389101' User entered '08 Aug 2020 22:10' | System           | 09 Aug 2020 03:10:10 |
|   | System           | 09 Aug 2020 03:10:10 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Aug 2020 22:07' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '09 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |



US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 2' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a' | System           | 09 Aug 2020 23:03:14 |
| User entered 'No interference with activity (1)'   | System           | 09 Aug 2020 23:03:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a' | System           | 09 Aug 2020 23:03:14 |
| User entered 'Some interference with activity (2)'   | System           | 09 Aug 2020 23:03:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:30', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a' User entered 'None (0)' | System           | 09 Aug 2020 23:03:14 |
|  | System           | 09 Aug 2020 23:03:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:34', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a' User entered 'None (0)' | System           | 09 Aug 2020 23:03:14 |
|  | System           | 09 Aug 2020 23:03:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a' | System           | 09 Aug 2020 23:03:14 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System           | 09 Aug 2020 23:03:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a' User entered 'None (0)' | System           | 09 Aug 2020 23:03:14 |
|  | System           | 09 Aug 2020 23:03:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:02:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a' User entered 'No (N)' | System           | 09 Aug 2020 23:03:14 |
|  | System           | 09 Aug 2020 23:03:14 |



US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-09T18:03:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044af38d-2b62-4b66-844e-daa9621bf54a' User entered '09 Aug 2020 18:03' | System           | 09 Aug 2020 23:03:14 |
|   | System           | 09 Aug 2020 23:03:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '09 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '10 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 3' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a' User entered 'None (0)' | System           | 10 Aug 2020 23:30:26 |
|  | System           | 10 Aug 2020 23:30:26 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:57', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a' | System           | 10 Aug 2020 23:30:26 |
| User entered 'No interference with activity (1)'   | System           | 10 Aug 2020 23:30:26 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:29:59', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a' User entered 'None (0)' | System           | 10 Aug 2020 23:30:26 |
|  | System           | 10 Aug 2020 23:30:26 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:30:02', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a' User entered 'None (0)' | System           | 10 Aug 2020 23:30:26 |
|  | System           | 10 Aug 2020 23:30:26 |



US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:30:05', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a' User entered 'None (0)' | System           | 10 Aug 2020 23:30:26 |
|  | System           | 10 Aug 2020 23:30:26 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:30:08', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a' User entered 'None (0)' | System           | 10 Aug 2020 23:30:26 |
|  | System           | 10 Aug 2020 23:30:26 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:30:11', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a' | System           | 10 Aug 2020 23:30:26 |
| User entered 'No (N)'  | System           | 10 Aug 2020 23:30:26 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-10T18:30:24', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c25676b9-5cd8-4f05-9de1-5e5d80ff242a' | System           | 10 Aug 2020 23:30:26 |
| User entered '10 Aug 2020 18:30'   | System           | 10 Aug 2020 23:30:26 |

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '10 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '11 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 4' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:16', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5cea6e7a57' | System           | 11 Aug 2020 21:58:47 |
| User entered 'None (0)'  | System           | 11 Aug 2020 21:58:47 |



US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:19', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5cea6e7a57' | System           | 11 Aug 2020 21:58:47 |
| User entered 'None (0)'  | System           | 11 Aug 2020 21:58:47 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5cea6e7a57' | System           | 11 Aug 2020 21:58:47 |
| User entered 'None (0)'  | System           | 11 Aug 2020 21:58:47 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5cea6e7a57' User entered 'None (0)' | System           | 11 Aug 2020 21:58:47 |
|  | System           | 11 Aug 2020 21:58:47 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:30', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5cea6e7a57' | System           | 11 Aug 2020 21:58:47 |
| User entered 'None (0)'  | System           | 11 Aug 2020 21:58:47 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

CHILLS

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:33', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5cea6e7a57' | System           | 11 Aug 2020 21:58:47 |
| User entered 'None (0)'  | System           | 11 Aug 2020 21:58:47 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5cea6e7a57' | System           | 11 Aug 2020 21:58:47 |
| User entered 'No (N)'  | System           | 11 Aug 2020 21:58:47 |

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-11T16:58:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7afb8161-aa5d-464a-9b31-af5cea6e7a57' | System           | 11 Aug 2020 21:58:47 |
| User entered '11 Aug 2020 16:58'   | System           | 11 Aug 2020 21:58:47 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '11 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |



US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '12 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 5' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aaeb15b7e8a' | System           | 12 Aug 2020 22:35:20 |
| User entered 'No interference with activity (1)'   | System           | 12 Aug 2020 22:35:20 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aaeb15b7e8a' | System           | 12 Aug 2020 22:35:20 |
| User entered 'No interference with activity (1)'   | System           | 12 Aug 2020 22:35:20 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:51', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aeb15b7e8a' User entered 'None (0)' | System           | 12 Aug 2020 22:35:20 |
|   | System           | 12 Aug 2020 22:35:20 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:34:56', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aueb15b7e8a' User entered 'None (0)' | System           | 12 Aug 2020 22:35:20 |
|  | System           | 12 Aug 2020 22:35:20 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:35:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aeb15b7e8a' User entered 'None (0)' | System           | 12 Aug 2020 22:35:20 |
|   | System           | 12 Aug 2020 22:35:20 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**CHILLS**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:35:03', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aeb15b7e8a' User entered 'None (0)' | System           | 12 Aug 2020 22:35:20 |
|   | System           | 12 Aug 2020 22:35:20 |



US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:35:06', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aeb15b7e8a' User entered 'No (N)' | System           | 12 Aug 2020 22:35:20 |
|   | System           | 12 Aug 2020 22:35:20 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-12T17:35:18', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2565f896-043d-4138-af35-9aaeb15b7e8a' User entered '12 Aug 2020 17:35' | System           | 12 Aug 2020 22:35:20 |
|   | System           | 12 Aug 2020 22:35:20 |

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '12 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '13 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 6' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1' User entered 'None (0)' | System           | 13 Aug 2020 22:25:13 |
|  | System           | 13 Aug 2020 22:25:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1' User entered 'None (0)' | System           | 13 Aug 2020 22:25:13 |
|  | System           | 13 Aug 2020 22:25:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1' User entered 'None (0)' | System           | 13 Aug 2020 22:25:13 |
|  | System           | 13 Aug 2020 22:25:13 |



US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1' User entered 'None (0)' | System           | 13 Aug 2020 22:25:13 |
|  | System           | 13 Aug 2020 22:25:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:54', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1' User entered 'None (0)' | System           | 13 Aug 2020 22:25:13 |
|  | System           | 13 Aug 2020 22:25:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

CHILLS

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:24:57', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1' User entered 'None (0)' | System           | 13 Aug 2020 22:25:13 |
|  | System           | 13 Aug 2020 22:25:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:25:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1' User entered 'No (N)' | System           | 13 Aug 2020 22:25:13 |
|  | System           | 13 Aug 2020 22:25:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-13T17:25:10', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7bc5e20d-59cb-4e03-927e-c8f9502983e1' User entered '13 Aug 2020 17:25' | System           | 13 Aug 2020 22:25:13 |
|   | System           | 13 Aug 2020 22:25:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '13 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '14 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 7' | System           | 08 Aug 2020 23:39:00 |



US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:37', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6' User entered 'None (0)' | System           | 14 Aug 2020 21:52:13 |
|  | System           | 14 Aug 2020 21:52:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6' User entered 'None (0)' | System           | 14 Aug 2020 21:52:13 |
|  | System           | 14 Aug 2020 21:52:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:42', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6' User entered 'None (0)' | System           | 14 Aug 2020 21:52:13 |
|  | System           | 14 Aug 2020 21:52:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6' User entered 'None (0)' | System           | 14 Aug 2020 21:52:13 |
|  | System           | 14 Aug 2020 21:52:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:51', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6' User entered 'None (0)' | System           | 14 Aug 2020 21:52:13 |
|  | System           | 14 Aug 2020 21:52:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6' User entered 'None (0)' | System           | 14 Aug 2020 21:52:13 |
|  | System           | 14 Aug 2020 21:52:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:51:56', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6' | System           | 14 Aug 2020 21:52:13 |
| User entered 'No (N)'  | System           | 14 Aug 2020 21:52:13 |

US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-14T16:52:11', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '79ffb750-f7b0-47be-b757-e2c982c7d6a6' | System           | 14 Aug 2020 21:52:13 |
| User entered '14 Aug 2020 16:52'   | System           | 14 Aug 2020 21:52:13 |



US3292103

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '14 Aug 2020 12:00' | System           | 08 Aug 2020 23:39:00 |

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '15 Aug 2020 11:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 13 Aug 2020 22:24:14 |
| User entered 'Day 8' | System           | 13 Aug 2020 22:24:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:30', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '6902b270-db18-49c8-978c-17f2f06a1c46' | System           | 15 Aug 2020 20:58:41 |
| User entered 'No (N)'  | System           | 15 Aug 2020 20:58:41 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-15T15:58:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '6902b270-db18-49c8-978c-17f2f06a1c46' | System           | 15 Aug 2020 20:58:41 |
| User entered '15 Aug 2020 15:58'   | System           | 15 Aug 2020 20:58:41 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '15 Aug 2020 12:00' | System           | 13 Aug 2020 22:24:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '16 Aug 2020 11:59' | System           | 13 Aug 2020 22:24:14 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 14 Aug 2020 21:51:11 |
| User entered 'Day 9' | System           | 14 Aug 2020 21:51:11 |



US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:46', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'fda66b09-a872-4271-bfd8-d9f6fc962e79' | System           | 16 Aug 2020 20:16:55 |
| User entered 'No (N)'  | System           | 16 Aug 2020 20:16:55 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-16T15:16:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'fda66b09-a872-4271-bfd8-d9f6fc962e79' User entered '16 Aug 2020 15:16' | System           | 16 Aug 2020 20:16:55 |
|   | System           | 16 Aug 2020 20:16:55 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '16 Aug 2020 12:00' | System           | 14 Aug 2020 21:51:11 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '17 Aug 2020 11:59' | System           | 14 Aug 2020 21:51:11 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 15 Aug 2020 20:58:29 |
| User entered 'Day 10' | System           | 15 Aug 2020 20:58:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1a018f38-b3ef-4470-aa55-389ccda08358' | System           | 17 Aug 2020 19:18:36 |
| User entered 'No (N)'  | System           | 17 Aug 2020 19:18:36 |

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-17T14:18:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1a018f38-b3ef-4470-aa55-389ccda08358' User entered '17 Aug 2020 14:18' | System           | 17 Aug 2020 19:18:36 |
|   | System           | 17 Aug 2020 19:18:36 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '17 Aug 2020 12:00' | System           | 15 Aug 2020 20:58:29 |



US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '18 Aug 2020 11:59' | System           | 15 Aug 2020 20:58:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 16 Aug 2020 20:16:46 |
| User entered 'Day 11' | System           | 16 Aug 2020 20:16:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:27', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '6a5efc9c-73b6-48db-ab9e-e567924458d0' | System           | 18 Aug 2020 21:07:35 |
| User entered 'No (N)'  | System           | 18 Aug 2020 21:07:35 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-18T16:07:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '6a5efc9c-73b6-48db-ab9e-e567924458d0' User entered '18 Aug 2020 16:07' | System           | 18 Aug 2020 21:07:35 |
|   | System           | 18 Aug 2020 21:07:35 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '18 Aug 2020 12:00' | System           | 16 Aug 2020 20:16:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '19 Aug 2020 11:59' | System           | 16 Aug 2020 20:16:46 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 17 Aug 2020 19:18:29 |
| User entered 'Day 12' | System           | 17 Aug 2020 19:18:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:56', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8f018c8a-35f3-4f4d-ade4-da9ef5932dd9' | System           | 19 Aug 2020 23:18:05 |
| User entered 'No (N)'  | System           | 19 Aug 2020 23:18:05 |



US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-19T18:17:59', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8f018c8a-35f3-4f4d-ade4-da9ef5932dd9' User entered '19 Aug 2020 18:17' | System           | 19 Aug 2020 23:18:05 |
|   | System           | 19 Aug 2020 23:18:05 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '19 Aug 2020 12:00' | System           | 17 Aug 2020 19:18:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '20 Aug 2020 11:59' | System           | 17 Aug 2020 19:18:29 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 18 Aug 2020 21:07:24 |
| User entered 'Day 13' | System           | 18 Aug 2020 21:07:24 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '81aff379-b4ff-4911-b277-3ca1a603f6ed' | System           | 20 Aug 2020 20:24:47 |
| User entered 'No (N)'  | System           | 20 Aug 2020 20:24:47 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-20T15:24:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '81aff379-b4ff-4911-b277-3ca1a603f6ed' User entered '20 Aug 2020 15:24' | System           | 20 Aug 2020 20:24:47 |
|   | System           | 20 Aug 2020 20:24:47 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '20 Aug 2020 12:00' | System           | 18 Aug 2020 21:07:24 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '21 Aug 2020 11:59' | System           | 18 Aug 2020 21:07:24 |



US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 19 Aug 2020 23:17:53 |
| User entered 'Day 14' | System           | 19 Aug 2020 23:17:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:55', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b698e6ec-016f-471e-b7b9-1d1d824a66b8' | System           | 22 Aug 2020 05:00:03 |
| User entered 'No (N)'  | System           | 22 Aug 2020 05:00:03 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-21T23:59:59', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b698e6ec-016f-471e-b7b9-1d1d824a66b8' User entered '21 Aug 2020 23:59' | System           | 22 Aug 2020 05:00:03 |
|   | System           | 22 Aug 2020 05:00:03 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '21 Aug 2020 12:00' | System           | 19 Aug 2020 23:17:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '22 Aug 2020 11:59' | System           | 19 Aug 2020 23:17:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 20 Aug 2020 20:24:42 |
| User entered 'Day 15' | System           | 20 Aug 2020 20:24:42 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ea367042-65cb-4433-b8e9-6606ead046f4' | System           | 22 Aug 2020 22:12:48 |
| User entered 'No (N)'  | System           | 22 Aug 2020 22:12:48 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-22T17:12:46', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ea367042-65cb-4433-b8e9-6606ead046f4' User entered '22 Aug 2020 17:12' | System           | 22 Aug 2020 22:12:48 |
|   | System           | 22 Aug 2020 22:12:48 |



US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '22 Aug 2020 12:00' | System           | 20 Aug 2020 20:24:42 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '23 Aug 2020 11:59' | System           | 20 Aug 2020 20:24:42 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 22 Aug 2020 04:59:53 |
| User entered 'Day 16' | System           | 22 Aug 2020 04:59:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:07:06', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'df56accb-89e9-4d20-ab02-5943c308b6ee' User entered 'No (N)' | System           | 23 Aug 2020 21:07:16 |
|  | System           | 23 Aug 2020 21:07:16 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-23T16:07:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'df56accb-89e9-4d20-ab02-5943c308b6ee' User entered '23 Aug 2020 16:07' | System           | 23 Aug 2020 21:07:16 |
|   | System           | 23 Aug 2020 21:07:16 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '23 Aug 2020 12:00' | System           | 22 Aug 2020 04:59:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(16)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '24 Aug 2020 11:59' | System           | 22 Aug 2020 04:59:53 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 22 Aug 2020 22:12:40 |
| User entered 'Day 17' | System           | 22 Aug 2020 22:12:40 |



US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-24T14:54:37', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3e281df7-3192-4233-b1f8-59bc513f1de1' User entered 'No (N)' | System           | 24 Aug 2020 19:54:43 |
|  | System           | 24 Aug 2020 19:54:43 |

**US3292103**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(17)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-08-24T14:54:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3e281df7-3192-4233-b1f8-59bc513f1de1' User entered '24 Aug 2020 14:54' | System           | 24 Aug 2020 19:54:43 |
|   | System           | 24 Aug 2020 19:54:43 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '24 Aug 2020 12:00' | System           | 22 Aug 2020 22:12:40 |

US3292103

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(17)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '25 Aug 2020 11:59' | System           | 22 Aug 2020 22:12:40 |

**US3292103**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Was Contact Attempted?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:08:05 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 19 Aug 2020 02:24:20 |

**US3292103**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 10 Mar 2021 16:08:05 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:07 |
| User entered '17 Aug 2020' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 19 Aug 2020 02:24:20 |

**US3292103**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.                        | (b) (4), (b) (6)                           | 10 Mar 2021 16:08:05 |
| User signature succeeded.                  | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 19 Aug 2020 02:24:20 |

US3292103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:08:05 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 19 Aug 2020 02:24:20 |



US3292103

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:20:34

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:08:11 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 19 Aug 2020 02:24:09 |

**US3292103**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'l'  | System           | 19 Aug 2020 02:24:09 |

US3292103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Was Contact Attempted?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                             | 10 Mar 2021 16:09:27 |
| User signature succeeded. | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 24 Aug 2020 19:51:09 |

US3292103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)                             | 10 Mar 2021 16:09:27 |
| User signature succeeded.  | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered '24 Aug 2020' | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 24 Aug 2020 19:51:09 |

US3292103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Please select one status for the follow-up contact](#)

| Audit                                      | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.                        | (b) (4), (b) (6)                             | 10 Mar 2021 16:09:27 |
| User signature succeeded.                  | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 24 Aug 2020 19:51:09 |

US3292103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                             | 10 Mar 2021 16:09:27 |
| User signature succeeded. | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 24 Aug 2020 19:51:09 |

US3292103

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:20:34

[Is the participant continuing to the next visit?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                             | 10 Mar 2021 16:09:39 |
| User signature succeeded. | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 24 Aug 2020 19:53:35 |

**US3292103**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'l'  | System           | 24 Aug 2020 19:53:35 |



**US3292103**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Was Contact Attempted?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                             | 10 Mar 2021 16:13:42 |
| User signature succeeded. | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 30 Aug 2020 02:41:25 |

**US3292103**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)                             | 10 Mar 2021 16:13:42 |
| User signature succeeded.  | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered '29 Aug 2020' | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 30 Aug 2020 02:41:25 |

US3292103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Please select one status for the follow-up contact](#)

| Audit                                      | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.                        | (b) (4), (b) (6)                             | 10 Mar 2021 16:13:42 |
| User signature succeeded.                  | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 30 Aug 2020 02:41:25 |

US3292103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                             | 10 Mar 2021 16:13:42 |
| User signature succeeded. | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 30 Aug 2020 02:41:25 |

US3292103

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:20:34

[Is the participant continuing to the next visit?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                             | 10 Mar 2021 16:13:50 |
| User signature succeeded. | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 30 Aug 2020 02:41:51 |

**US3292103**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'l'  | System           | 30 Aug 2020 02:41:51 |

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Was this visit performed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:15:03 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:14:02 |

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:15:03 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '5 Sep 2020' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:14:02 |



US3292103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:20:34

[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 14:20:53 |
| DataPoint Verified.            | (b) (4), (b) (6)                           | 10 Mar 2021 16:15:03 |
| User signature succeeded.      | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:14:02 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:20:34

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'VISIT2' | System           | 05 Sep 2020 19:14:02 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                | 14 Apr 2021 14:20:53 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:15:12 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Were vital signs assessed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:15:12 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '5 Sep 2020' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:15:12 |

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '12:33'      | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:15:12 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered '5 Sep 2020 12:33' | System           | 05 Sep 2020 19:15:12 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

Temperature (xxx.x)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '36.4' C     | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:15:12 |



US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Route of measurement](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered 'Oral (Oral)' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:15:12 |

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:20:34**

[If Other, specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:15:12 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Pulse \(xxx\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '79'         | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:15:12 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'bpm' | System           | 05 Sep 2020 19:15:12 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '16'         | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:15:12 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'breaths/min' | System           | 05 Sep 2020 19:15:12 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

Systolic Blood Pressure (xxx)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '137'        | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:15:12 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'mmHg' | System           | 05 Sep 2020 19:15:12 |



US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

Diastolic Blood Pressure (xxx)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '74'         | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:15:12 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:20:34

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'mmHg' | System           | 05 Sep 2020 19:15:12 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                | 14 Apr 2021 14:20:53 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:04 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Were vital signs assessed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:04 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '5 Sep 2020' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:04 |

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:20:34**

**Time of assessment (00:00-23:59)**

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '13:51'      | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:04 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered '5 Sep 2020 13:51' | System           | 05 Sep 2020 19:16:04 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

Temperature (xxx.x)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '36.7' C     | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:04 |



US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Route of measurement](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered 'Oral (Oral)' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:04 |

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:20:34**

[If Other, specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:04 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Pulse \(xxx\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '75'         | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:04 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'bpm' | System           | 05 Sep 2020 19:16:04 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '16'         | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:04 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'breaths/min' | System           | 05 Sep 2020 19:16:04 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

Systolic Blood Pressure (xxx)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '127'        | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:04 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'mmHg' | System           | 05 Sep 2020 19:16:04 |



US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

Diastolic Blood Pressure (xxx)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 18:09:45 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '76'         | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:04 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:20:34

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'mmHg' | System           | 05 Sep 2020 19:16:04 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:20:34

[Was the physical examination performed?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:17:03 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:18 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:20:34

Date of examination (dd MMM yyyy)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:17:03 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '5 Sep 2020' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:18 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[Was study treatment given?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:17:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 05 Sep 2020 18:30:38 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[If No, reason not given](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:17:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 05 Sep 2020 18:30:38 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:17:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 05 Sep 2020 18:30:38 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 05 Sep 2020 18:30:38 |



US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:17:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '5 Sep 2020' | (b) (4), (b) (6)       | 05 Sep 2020 18:30:38 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:17:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '13:21'      | (b) (4), (b) (6)       | 05 Sep 2020 18:30:38 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[Treatment Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered '5 Sep 2020 13:21' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[Which arm was used to give treatment?](#)

| Audit                              | User                   | Time (GMT)           |
|------------------------------------|------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.                | (b) (4), (b) (6)       | 10 Mar 2021 16:17:45 |
| User signature succeeded.          | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6)       | 05 Sep 2020 18:30:38 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 16:17:45 |
| User entered 'ONCE' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:20:34

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'INTRAMUSCULAR' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

[Was the sample collected?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:20:54 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:37 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

Collection date (dd MMM yyyy)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:20:54 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '5 Sep 2020' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:37 |



US3292103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

Collection time (00:00-23:59)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:20:54 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '12:42'      | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:37 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered '5 Sep 2020 12:42' | System           | 05 Sep 2020 19:16:37 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:20:34

Collection date (dd MMM yyyy)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:21:09 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '5 Sep 2020' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:54 |

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Lab Test](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 14 Apr 2021 14:20:53 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:54 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:20:34

[Was the sample collected?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:21:09 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:54 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:20:34

Collection time (00:00 - 23:59)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:21:09 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered '12:48'      | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:54 |

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered '5 Sep 2020 12:48' | System           | 05 Sep 2020 19:16:54 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:20:34

[Lab Test](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 14 Apr 2021 14:20:53 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:54 |



US3292103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:20:34

[Was the sample collected?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:21:09 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:54 |

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:20:34**

**Collection time (00:00 - 23:59)**

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:21:09 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:16:54 |

**US3292103**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered empty. | System           | 05 Sep 2020 19:16:54 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:20:34

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:28:05 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 05 Sep 2020 19:17:06 |

US3292103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:20:34

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'l'  | System           | 05 Sep 2020 19:17:06 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8b54c32c-987b-4253-b772-e41e08e71962' User entered 'Yes (Y)' | System           | 05 Sep 2020 18:54:40 |
|   | System           | 05 Sep 2020 18:54:40 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8b54c32c-987b-4253-b772-e41e08e71962' User entered '98.0' | System           | 05 Sep 2020 18:54:40 |
|  | System           | 05 Sep 2020 18:54:40 |



US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8b54c32c-987b-4253-b772-e41e08e71962' | System           | 05 Sep 2020 18:54:40 |
| User entered 'No (N)'  | System           | 05 Sep 2020 18:54:40 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8b54c32c-987b-4253-b772-e41e08e71962' | System           | 05 Sep 2020 18:54:40 |
| User entered '05 Sep 2020 13:54'   | System           | 05 Sep 2020 18:54:40 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '05 Sep 2020 13:41' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '05 Sep 2020 16:11' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.                                | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 1, after vaccination (at home)' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:33:34', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '043294c0-c30e-4817-aa53-f758e0b165c6' User entered 'Yes (Y)' | System           | 06 Sep 2020 00:33:52 |
|   | System           | 06 Sep 2020 00:33:52 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:33:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '043294c0-c30e-4817-aa53-f758e0b165c6' User entered '97.7' | System           | 06 Sep 2020 00:33:52 |
|  | System           | 06 Sep 2020 00:33:52 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:33:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '043294c0-c30e-4817-aa53-f758e0b165c6' | System           | 06 Sep 2020 00:33:52 |
| User entered 'No (N)'  | System           | 06 Sep 2020 00:33:52 |



US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:33:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '043294c0-c30e-4817-aa53-f758e0b165c6' User entered '05 Sep 2020 19:33' | System           | 06 Sep 2020 00:33:52 |
|   | System           | 06 Sep 2020 00:33:52 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '05 Sep 2020 17:06' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '06 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 2' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:30:55', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bb6fb165-1836-4676-98d5-40cc22437c2a' User entered 'Yes (Y)' | System           | 06 Sep 2020 23:31:13 |
|   | System           | 06 Sep 2020 23:31:13 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bb6fb165-1836-4676-98d5-40cc22437c2a' User entered '98.2' | System           | 06 Sep 2020 23:31:13 |
|  | System           | 06 Sep 2020 23:31:13 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:03', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bb6fb165-1836-4676-98d5-40cc22437c2a' | System           | 06 Sep 2020 23:31:13 |
| User entered 'No (N)'  | System           | 06 Sep 2020 23:31:13 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bb6fb165-1836-4676-98d5-40cc22437c2a' User entered '06 Sep 2020 18:31' | System           | 06 Sep 2020 23:31:13 |
|   | System           | 06 Sep 2020 23:31:13 |



US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '06 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '07 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 3' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:03:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '78826bb7-1f89-4a73-9767-9a7472aaab16' User entered 'Yes (Y)' | System           | 07 Sep 2020 22:03:53 |
|   | System           | 07 Sep 2020 22:03:53 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:03:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '78826bb7-1f89-4a73-9767-9a7472aaab16' User entered '98.2' | System           | 07 Sep 2020 22:03:53 |
|  | System           | 07 Sep 2020 22:03:53 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:03:46', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '78826bb7-1f89-4a73-9767-9a7472aaab16' User entered 'No (N)' | System           | 07 Sep 2020 22:03:53 |
|  | System           | 07 Sep 2020 22:03:53 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:03:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '78826bb7-1f89-4a73-9767-9a7472aaab16' User entered '07 Sep 2020 17:03' | System           | 07 Sep 2020 22:03:53 |
|   | System           | 07 Sep 2020 22:03:53 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '07 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |



US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 4' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:13:59', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e07d04b9-0f09-4540-916f-063ead6c981a' User entered 'Yes (Y)' | System           | 09 Sep 2020 00:14:14 |
|   | System           | 09 Sep 2020 00:14:14 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:03', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e07d04b9-0f09-4540-916f-063ead6c981a' User entered '98.0' | System           | 09 Sep 2020 00:14:14 |
|  | System           | 09 Sep 2020 00:14:14 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:06', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e07d04b9-0f09-4540-916f-063ead6c981a' User entered 'No (N)' | System           | 09 Sep 2020 00:14:14 |
|  | System           | 09 Sep 2020 00:14:14 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:11', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e07d04b9-0f09-4540-916f-063ead6c981a' User entered '08 Sep 2020 19:14' | System           | 09 Sep 2020 00:14:14 |
|   | System           | 09 Sep 2020 00:14:14 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '09 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |



US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 5' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:14:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a6256e47-8bf6-4fbf-92ab-8a510a66b033' | System           | 09 Sep 2020 22:14:51 |
| User entered 'Yes (Y)'   | System           | 09 Sep 2020 22:14:51 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:14:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a6256e47-8bf6-4fbf-92ab-8a510a66b033' | System           | 09 Sep 2020 22:14:51 |
| User entered '98.0'  | System           | 09 Sep 2020 22:14:51 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:14:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a6256e47-8bf6-4fbf-92ab-8a510a66b033' | System           | 09 Sep 2020 22:14:51 |
| User entered 'No (N)'  | System           | 09 Sep 2020 22:14:51 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:14:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a6256e47-8bf6-4fbf-92ab-8a510a66b033' | System           | 09 Sep 2020 22:14:51 |
| User entered '09 Sep 2020 17:14'   | System           | 09 Sep 2020 22:14:51 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '09 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '10 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 6' | System           | 05 Sep 2020 18:30:38 |



US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:33:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'cf552e68-a4c6-4973-b946-6520b7d19116' User entered 'Yes (Y)' | System           | 10 Sep 2020 23:33:55 |
|   | System           | 10 Sep 2020 23:33:55 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:33:44', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'cf552e68-a4c6-4973-b946-6520b7d19116' User entered '98.0' | System           | 10 Sep 2020 23:33:55 |
|  | System           | 10 Sep 2020 23:33:55 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:33:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'cf552e68-a4c6-4973-b946-6520b7d19116' User entered 'No (N)' | System           | 10 Sep 2020 23:33:55 |
|  | System           | 10 Sep 2020 23:33:55 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:33:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'cf552e68-a4c6-4973-b946-6520b7d19116' User entered '10 Sep 2020 18:33' | System           | 10 Sep 2020 23:33:55 |
|   | System           | 10 Sep 2020 23:33:55 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '10 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '11 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 7' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3d13d264-e06b-4285-b0fa-2011a351486e' User entered 'Yes (Y)' | System           | 11 Sep 2020 22:32:54 |
|   | System           | 11 Sep 2020 22:32:54 |



US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3d13d264-e06b-4285-b0fa-2011a351486e' User entered '98.0' | System           | 11 Sep 2020 22:32:54 |
|  | System           | 11 Sep 2020 22:32:54 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:16', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3d13d264-e06b-4285-b0fa-2011a351486e' User entered 'No (N)' | System           | 11 Sep 2020 22:32:54 |
|  | System           | 11 Sep 2020 22:32:54 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3d13d264-e06b-4285-b0fa-2011a351486e' User entered '11 Sep 2020 17:32' | System           | 11 Sep 2020 22:32:54 |
|   | System           | 11 Sep 2020 22:32:54 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '11 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '12 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933bae30-ee5c-4b4f-8d90-b1c648e30b8d' User entered 'None (1)' | System           | 05 Sep 2020 18:54:58 |
|  | System           | 05 Sep 2020 18:54:58 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933bae30-ee5c-4b4f-8d90-b1c648e30b8d' User entered 'No (N)' | System           | 05 Sep 2020 18:54:58 |
|  | System           | 05 Sep 2020 18:54:58 |



US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933bae30-ee5c-4b4f-8d90-b1c648e30b8d' User entered 'No (N)' | System           | 05 Sep 2020 18:54:58 |
|  | System           | 05 Sep 2020 18:54:58 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933bae30-ee5c-4b4f-8d90-b1c648e30b8d' User entered 'None (1)' | System           | 05 Sep 2020 18:54:58 |
|  | System           | 05 Sep 2020 18:54:58 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:54:56', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '933bae30-ee5c-4b4f-8d90-b1c648e30b8d' User entered '05 Sep 2020 13:54' | System           | 05 Sep 2020 18:54:58 |
|   | System           | 05 Sep 2020 18:54:58 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '05 Sep 2020 13:41' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '05 Sep 2020 16:11' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.                                | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 1, after vaccination (at home)' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:33:56', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7128b11b-0367-4103-b957-1c3f6a830804' | System           | 06 Sep 2020 00:34:20 |
| User entered 'Does not interfere with activity (2)'  | System           | 06 Sep 2020 00:34:20 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7128b11b-0367-4103-b957-1c3f6a830804' User entered 'No (N)' | System           | 06 Sep 2020 00:34:20 |
|  | System           | 06 Sep 2020 00:34:20 |



US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7128b11b-0367-4103-b957-1c3f6a830804' User entered 'No (N)' | System           | 06 Sep 2020 00:34:20 |
|  | System           | 06 Sep 2020 00:34:20 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7128b11b-0367-4103-b957-1c3f6a830804' | System           | 06 Sep 2020 00:34:20 |
| User entered 'None (1)'  | System           | 06 Sep 2020 00:34:20 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:17', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7128b11b-0367-4103-b957-1c3f6a830804' User entered '05 Sep 2020 19:34' | System           | 06 Sep 2020 00:34:20 |
|   | System           | 06 Sep 2020 00:34:20 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '05 Sep 2020 17:06' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '06 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 2' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:14', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c51cd2e6-6a88-4ebc-a040-cb7291fb08dd' | System           | 06 Sep 2020 23:32:06 |
| User entered 'Does not interfere with activity (2)'  | System           | 06 Sep 2020 23:32:06 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:18', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c51cd2e6-6a88-4ebc-a040-cb7291fb08dd' User entered 'No (N)' | System           | 06 Sep 2020 23:32:06 |
|  | System           | 06 Sep 2020 23:32:06 |



US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c51cd2e6-6a88-4ebc-a040-cb7291fb08dd' User entered 'No (N)' | System           | 06 Sep 2020 23:32:06 |
|  | System           | 06 Sep 2020 23:32:06 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:31:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c51cd2e6-6a88-4ebc-a040-cb7291fb08dd' | System           | 06 Sep 2020 23:32:06 |
| User entered 'None (1)'  | System           | 06 Sep 2020 23:32:06 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:02', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c51cd2e6-6a88-4ebc-a040-cb7291fb08dd' User entered '06 Sep 2020 18:32' | System           | 06 Sep 2020 23:32:06 |
|   | System           | 06 Sep 2020 23:32:06 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '06 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '07 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 3' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:03:57', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b908ef6b-e4ac-4210-8950-c1af38aeb4ea' | System           | 07 Sep 2020 22:04:15 |
| User entered 'Does not interfere with activity (2)'  | System           | 07 Sep 2020 22:04:15 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b908cf6b-e4ac-4210-8950-c1af38aeb4ea' User entered 'No (N)' | System           | 07 Sep 2020 22:04:15 |
|  | System           | 07 Sep 2020 22:04:15 |



US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b908cf6b-e4ac-4210-8950-c1af38aeb4ea' User entered 'No (N)' | System           | 07 Sep 2020 22:04:15 |
|  | System           | 07 Sep 2020 22:04:15 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:10', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b908ef6b-e4ac-4210-8950-c1af38aeb4ea' User entered 'None (1)' | System           | 07 Sep 2020 22:04:15 |
|  | System           | 07 Sep 2020 22:04:15 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:13', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b908ef6b-e4ac-4210-8950-c1af38aeb4ea' User entered '07 Sep 2020 17:04' | System           | 07 Sep 2020 22:04:15 |
|   | System           | 07 Sep 2020 22:04:15 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '07 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 4' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:19', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044f52ec-df5e-41d6-99a7-1e40649f66af' User entered 'Does not interfere with activity (2)' | System           | 09 Sep 2020 00:14:33 |
|  | System           | 09 Sep 2020 00:14:33 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:22', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044f52ec-df5e-41d6-99a7-1e40649f66af' User entered 'No (N)' | System           | 09 Sep 2020 00:14:33 |
|  | System           | 09 Sep 2020 00:14:33 |



US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044f52ec-df5e-41d6-99a7-1e40649f66af' User entered 'No (N)' | System           | 09 Sep 2020 00:14:33 |
|  | System           | 09 Sep 2020 00:14:33 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:27', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044f52ee-df5e-41d6-99a7-1e40649f66af' User entered 'None (1)' | System           | 09 Sep 2020 00:14:33 |
|  | System           | 09 Sep 2020 00:14:33 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:30', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '044f52ec-df5e-41d6-99a7-1e40649f66af' User entered '08 Sep 2020 19:14' | System           | 09 Sep 2020 00:14:33 |
|   | System           | 09 Sep 2020 00:14:33 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '09 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 5' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:14:57', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3bb5a348-e842-41ab-8224-80ef6059149f' User entered 'Does not interfere with activity (2)' | System           | 09 Sep 2020 22:15:17 |
|  | System           | 09 Sep 2020 22:15:17 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:01', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3bb5a348-e842-41ab-8224-80ef6059149f' User entered 'No (N)' | System           | 09 Sep 2020 22:15:17 |
|  | System           | 09 Sep 2020 22:15:17 |



US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:06', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3bb5a348-e842-41ab-8224-80ef6059149f' User entered 'No (N)' | System           | 09 Sep 2020 22:15:17 |
|  | System           | 09 Sep 2020 22:15:17 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3bb5a348-e842-41ab-8224-80ef6059149f' User entered 'None (1)' | System           | 09 Sep 2020 22:15:17 |
|  | System           | 09 Sep 2020 22:15:17 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '3bb5a348-e842-41ab-8224-80ef6059149f' User entered '09 Sep 2020 17:15' | System           | 09 Sep 2020 22:15:17 |
|   | System           | 09 Sep 2020 22:15:17 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '09 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '10 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 6' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:03', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '60305789-a5b1-4f7d-b4fa-3d363e7e70e7' | System           | 10 Sep 2020 23:34:21 |
| User entered 'Does not interfere with activity (2)'  | System           | 10 Sep 2020 23:34:21 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:06', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '60305789-a5b1-4f7d-b4fa-3d363e7e70e7' User entered 'No (N)' | System           | 10 Sep 2020 23:34:21 |
|  | System           | 10 Sep 2020 23:34:21 |



US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:08', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '60305789-a5b1-4f7d-b4fa-3d363e7e70e7' User entered 'No (N)' | System           | 10 Sep 2020 23:34:21 |
|  | System           | 10 Sep 2020 23:34:21 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '60305789-a5b1-4f7d-b4fa-3d363e7e70e7' | System           | 10 Sep 2020 23:34:21 |
| User entered 'None (1)'  | System           | 10 Sep 2020 23:34:21 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:19', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '60305789-a5b1-4f7d-b4fa-3d363e7e70e7' User entered '10 Sep 2020 18:34' | System           | 10 Sep 2020 23:34:21 |
|   | System           | 10 Sep 2020 23:34:21 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '10 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '11 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 7' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b8d1b372-9bcf-4bf8-b122-8617cdd3d5ee' | System           | 11 Sep 2020 22:33:00 |
| User entered 'Does not interfere with activity (2)'  | System           | 11 Sep 2020 22:33:00 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b8d1b372-9bcf-4bf8-b122-8617cdd3d5ee' User entered 'No (N)' | System           | 11 Sep 2020 22:33:00 |
|  | System           | 11 Sep 2020 22:33:00 |



US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:33', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b8d1b372-9bcf-4bf8-b122-8617cdd3d5ee' User entered 'No (N)' | System           | 11 Sep 2020 22:33:00 |
|  | System           | 11 Sep 2020 22:33:00 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b8d1b372-9bcf-4bf8-b122-8617cdd3d5ee' | System           | 11 Sep 2020 22:33:00 |
| User entered 'None (1)'  | System           | 11 Sep 2020 22:33:00 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:42', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'b8d1b372-9bcf-4bf8-b122-8617cdd3d5ee' User entered '11 Sep 2020 17:32' | System           | 11 Sep 2020 22:33:00 |
|   | System           | 11 Sep 2020 22:33:00 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '11 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '12 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

TIMEPOINT

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:02', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01' User entered 'None (0)' | System           | 05 Sep 2020 18:55:29 |
|  | System           | 05 Sep 2020 18:55:29 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:05', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01' User entered 'None (0)' | System           | 05 Sep 2020 18:55:29 |
|  | System           | 05 Sep 2020 18:55:29 |



US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:08', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01' User entered 'None (0)' | System           | 05 Sep 2020 18:55:29 |
|  | System           | 05 Sep 2020 18:55:29 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:10', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01' User entered 'None (0)' | System           | 05 Sep 2020 18:55:29 |
|  | System           | 05 Sep 2020 18:55:29 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:13', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01' User entered 'None (0)' | System           | 05 Sep 2020 18:55:29 |
|  | System           | 05 Sep 2020 18:55:29 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01' User entered 'None (0)' | System           | 05 Sep 2020 18:55:29 |
|  | System           | 05 Sep 2020 18:55:29 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:23', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01' User entered 'No (N)' | System           | 05 Sep 2020 18:55:29 |
|  | System           | 05 Sep 2020 18:55:29 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T13:55:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8d24bd89-8d08-4117-a5e3-27c8e273ce01' User entered '05 Sep 2020 13:55' | System           | 05 Sep 2020 18:55:29 |
|   | System           | 05 Sep 2020 18:55:29 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '05 Sep 2020 13:41' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '05 Sep 2020 16:11' | System           | 05 Sep 2020 18:30:38 |



US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.                                | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 1, after vaccination (at home)' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:24', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5' User entered 'None (0)' | System           | 06 Sep 2020 00:34:57 |
|  | System           | 06 Sep 2020 00:34:57 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:30', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5' | System           | 06 Sep 2020 00:34:57 |
| User entered 'No interference with activity (1)'   | System           | 06 Sep 2020 00:34:57 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:32', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5' User entered 'None (0)' | System           | 06 Sep 2020 00:34:57 |
|  | System           | 06 Sep 2020 00:34:57 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5' User entered 'None (0)' | System           | 06 Sep 2020 00:34:57 |
|  | System           | 06 Sep 2020 00:34:57 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5' User entered 'None (0)' | System           | 06 Sep 2020 00:34:57 |
|  | System           | 06 Sep 2020 00:34:57 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5' User entered 'None (0)' | System           | 06 Sep 2020 00:34:57 |
|  | System           | 06 Sep 2020 00:34:57 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:46', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5' User entered 'No (N)' | System           | 06 Sep 2020 00:34:57 |
|  | System           | 06 Sep 2020 00:34:57 |



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-05T19:34:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd8ede341-97a7-419f-bc78-e1eb440c06d5' User entered '05 Sep 2020 19:34' | System           | 06 Sep 2020 00:34:57 |
|   | System           | 06 Sep 2020 00:34:57 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '05 Sep 2020 17:06' | System           | 05 Sep 2020 18:30:38 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '06 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 2' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:08', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24' | System           | 06 Sep 2020 23:32:51 |
| User entered 'No interference with activity (1)'   | System           | 06 Sep 2020 23:32:51 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:11', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24' | System           | 06 Sep 2020 23:32:51 |
| User entered 'Some interference with activity (2)'   | System           | 06 Sep 2020 23:32:51 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:15', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24' User entered 'None (0)' | System           | 06 Sep 2020 23:32:51 |
|  | System           | 06 Sep 2020 23:32:51 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:18', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24' User entered 'None (0)' | System           | 06 Sep 2020 23:32:51 |
|  | System           | 06 Sep 2020 23:32:51 |



US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:23', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24' | System           | 06 Sep 2020 23:32:51 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System           | 06 Sep 2020 23:32:51 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24' User entered 'None (0)' | System           | 06 Sep 2020 23:32:51 |
|  | System           | 06 Sep 2020 23:32:51 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:29', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24' | System           | 06 Sep 2020 23:32:51 |
| User entered 'No (N)'  | System           | 06 Sep 2020 23:32:51 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-06T18:32:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1d78fbbf-0b41-41b4-aef6-bfd6c23f5a24' | System           | 06 Sep 2020 23:32:51 |
| User entered '06 Sep 2020 18:32'   | System           | 06 Sep 2020 23:32:51 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '06 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '07 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 3' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:17', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60' User entered 'None (0)' | System           | 07 Sep 2020 22:04:38 |
|  | System           | 07 Sep 2020 22:04:38 |



US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:20', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60' User entered 'None (0)' | System           | 07 Sep 2020 22:04:38 |
|  | System           | 07 Sep 2020 22:04:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:22', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60' User entered 'None (0)' | System           | 07 Sep 2020 22:04:38 |
|  | System           | 07 Sep 2020 22:04:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60' User entered 'None (0)' | System           | 07 Sep 2020 22:04:38 |
|  | System           | 07 Sep 2020 22:04:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60' User entered 'None (0)' | System           | 07 Sep 2020 22:04:38 |
|  | System           | 07 Sep 2020 22:04:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

CHILLS

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60' User entered 'None (0)' | System           | 07 Sep 2020 22:04:38 |
|  | System           | 07 Sep 2020 22:04:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:34', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60' User entered 'No (N)' | System           | 07 Sep 2020 22:04:38 |
|  | System           | 07 Sep 2020 22:04:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-07T17:04:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'da6e53cd-dbb1-4dbe-aaa5-0c93ea631e60' User entered '07 Sep 2020 17:04' | System           | 07 Sep 2020 22:04:38 |
|   | System           | 07 Sep 2020 22:04:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '07 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 4' | System           | 05 Sep 2020 18:30:38 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:20:34**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fac-f943-4692-adaa-8cdda3edabe2' User entered 'None (0)' | System           | 09 Sep 2020 00:14:57 |
|  | System           | 09 Sep 2020 00:14:57 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:39', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fac-f943-4692-adaa-8cdda3edabc2' User entered 'None (0)' | System           | 09 Sep 2020 00:14:57 |
|  | System           | 09 Sep 2020 00:14:57 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fac-f943-4692-adaa-8cdda3edabe2' User entered 'None (0)' | System           | 09 Sep 2020 00:14:57 |
|  | System           | 09 Sep 2020 00:14:57 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fac-f943-4692-adaa-8cdda3edabe2' User entered 'None (0)' | System           | 09 Sep 2020 00:14:57 |
|  | System           | 09 Sep 2020 00:14:57 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fac-f943-4692-adaa-8cdda3edabe2' User entered 'None (0)' | System           | 09 Sep 2020 00:14:57 |
|  | System           | 09 Sep 2020 00:14:57 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fac-f943-4692-adaa-8cdda3edabe2' User entered 'None (0)' | System           | 09 Sep 2020 00:14:57 |
|  | System           | 09 Sep 2020 00:14:57 |



US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fac-f943-4692-adaa-8cdda3edabe2' User entered 'No (N)' | System           | 09 Sep 2020 00:14:57 |
|  | System           | 09 Sep 2020 00:14:57 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-08T19:14:55', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'a7207fac-f943-4692-adaa-8cd da3edabc2' User entered '08 Sep 2020 19:14' | System           | 09 Sep 2020 00:14:57 |
|  | System           | 09 Sep 2020 00:14:57 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '08 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '09 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 5' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:16', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465' User entered 'None (0)' | System           | 09 Sep 2020 22:15:59 |
|  | System           | 09 Sep 2020 22:15:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:19', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465' User entered 'None (0)' | System           | 09 Sep 2020 22:15:59 |
|  | System           | 09 Sep 2020 22:15:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465' User entered 'None (0)' | System           | 09 Sep 2020 22:15:59 |
|  | System           | 09 Sep 2020 22:15:59 |



US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465' User entered 'None (0)' | System           | 09 Sep 2020 22:15:59 |
|  | System           | 09 Sep 2020 22:15:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465' User entered 'None (0)' | System           | 09 Sep 2020 22:15:59 |
|  | System           | 09 Sep 2020 22:15:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

CHILLS

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465' User entered 'None (0)' | System           | 09 Sep 2020 22:15:59 |
|  | System           | 09 Sep 2020 22:15:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465' | System           | 09 Sep 2020 22:15:59 |
| User entered 'No (N)'  | System           | 09 Sep 2020 22:15:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-09T17:15:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '1745ff90-66ef-4393-b4aa-a12a7616f465' | System           | 09 Sep 2020 22:15:59 |
| User entered '09 Sep 2020 17:15'   | System           | 09 Sep 2020 22:15:59 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '09 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '10 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 6' | System           | 05 Sep 2020 18:30:38 |



US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:24', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416' User entered 'None (0)' | System           | 10 Sep 2020 23:34:49 |
|  | System           | 10 Sep 2020 23:34:49 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416' User entered 'None (0)' | System           | 10 Sep 2020 23:34:49 |
|  | System           | 10 Sep 2020 23:34:49 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:28', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416' User entered 'None (0)' | System           | 10 Sep 2020 23:34:49 |
|  | System           | 10 Sep 2020 23:34:49 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416' User entered 'None (0)' | System           | 10 Sep 2020 23:34:49 |
|  | System           | 10 Sep 2020 23:34:49 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:33', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416' User entered 'None (0)' | System           | 10 Sep 2020 23:34:49 |
|  | System           | 10 Sep 2020 23:34:49 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

CHILLS

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416' User entered 'None (0)' | System           | 10 Sep 2020 23:34:49 |
|  | System           | 10 Sep 2020 23:34:49 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416' User entered 'No (N)' | System           | 10 Sep 2020 23:34:49 |
|  | System           | 10 Sep 2020 23:34:49 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-10T18:34:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '14eb93aa-8595-475c-bc9e-2e9c169fb416' User entered '10 Sep 2020 18:34' | System           | 10 Sep 2020 23:34:49 |
|   | System           | 10 Sep 2020 23:34:49 |



**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '10 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '11 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 05 Sep 2020 18:30:38 |
| User entered 'Day 7' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:46', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412' | System           | 11 Sep 2020 22:33:18 |
| User entered 'None (0)'  | System           | 11 Sep 2020 22:33:18 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:48', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412' | System           | 11 Sep 2020 22:33:18 |
| User entered 'None (0)'  | System           | 11 Sep 2020 22:33:18 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412' User entered 'None (0)' | System           | 11 Sep 2020 22:33:18 |
|  | System           | 11 Sep 2020 22:33:18 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412' User entered 'None (0)' | System           | 11 Sep 2020 22:33:18 |
|  | System           | 11 Sep 2020 22:33:18 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:55', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412' User entered 'None (0)' | System           | 11 Sep 2020 22:33:18 |
|  | System           | 11 Sep 2020 22:33:18 |



US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:32:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412' | System           | 11 Sep 2020 22:33:18 |
| User entered 'None (0)'  | System           | 11 Sep 2020 22:33:18 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:33:01', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412' | System           | 11 Sep 2020 22:33:18 |
| User entered 'No (N)'  | System           | 11 Sep 2020 22:33:18 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-11T17:33:10', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2c7ec7ea-df99-45d3-a8f0-b3c2a3178412' | System           | 11 Sep 2020 22:33:18 |
| User entered '11 Sep 2020 17:33'   | System           | 11 Sep 2020 22:33:18 |

US3292103

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '11 Sep 2020 12:00' | System           | 05 Sep 2020 18:30:38 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '12 Sep 2020 11:59' | System           | 05 Sep 2020 18:30:38 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 10 Sep 2020 23:34:21 |
| User entered 'Day 8' | System           | 10 Sep 2020 23:34:21 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 16:20:34

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-12T12:21:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '58438b66-77cf-4ac7-a750-d5efc409ad05' | System           | 12 Sep 2020 17:21:42 |
| User entered 'None (1)'  | System           | 12 Sep 2020 17:21:42 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 16:20:34

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-12T12:21:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '58438b66-77cf-4ac7-a750-d5efc409ad05' | System           | 12 Sep 2020 17:21:42 |
| User entered '12 Sep 2020 12:21'   | System           | 12 Sep 2020 17:21:42 |



US3292103

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '12 Sep 2020 12:00' | System           | 10 Sep 2020 23:34:21 |

US3292103

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 16:20:34

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '13 Sep 2020 11:59' | System           | 10 Sep 2020 23:34:21 |

US3292103

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.   | System           | 10 Sep 2020 23:34:21 |
| User entered 'Day 8' | System           | 10 Sep 2020 23:34:21 |

US3292103

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:20:34

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-12T12:21:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '375cb104-63b5-4243-b894-dead74d4461e' User entered 'No (N)' | System           | 12 Sep 2020 17:21:52 |
|  | System           | 12 Sep 2020 17:21:52 |

US3292103

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:20:34

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-09-12T12:21:49', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '375cb104-63b5-4243-b894-dead74d4461e' User entered '12 Sep 2020 12:21' | System           | 12 Sep 2020 17:21:52 |
|   | System           | 12 Sep 2020 17:21:52 |

US3292103

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 16:20:34

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '12 Sep 2020 12:00' | System           | 10 Sep 2020 23:34:21 |

**US3292103**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 16:20:34**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| User entered '13 Sep 2020 11:59' | System           | 10 Sep 2020 23:34:21 |

**US3292103**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Was Contact Attempted?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                             | 10 Mar 2021 16:42:12 |
| User signature succeeded. | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 14 Sep 2020 18:35:49 |



US3292103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)                             | 10 Mar 2021 16:42:12 |
| User signature succeeded.  | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered '14 Sep 2020' | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 14 Sep 2020 18:35:49 |

US3292103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Please select one status for the follow-up contact](#)

| Audit                                      | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.                        | (b) (4), (b) (6)                             | 10 Mar 2021 16:42:12 |
| User signature succeeded.                  | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 14 Sep 2020 18:35:49 |

US3292103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                             | 10 Mar 2021 16:42:12 |
| User signature succeeded. | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 14 Sep 2020 18:35:49 |

US3292103

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:20:34

[Is the participant continuing to the next visit?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)                             | 10 Mar 2021 16:42:27 |
| User signature succeeded. | Douglas Denham (b) (4)                       | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 14 Sep 2020 18:36:19 |

**US3292103**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'l'  | System           | 14 Sep 2020 18:36:19 |

US3292103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Was Contact Attempted?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:42:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 22 Sep 2020 16:36:27 |

**US3292103**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 10 Mar 2021 16:42:57 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '22 Sep 2020' | (b) (4), (b) (6)       | 22 Sep 2020 16:36:27 |

**US3292103**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.                        | (b) (4), (b) (6)       | 10 Mar 2021 16:42:57 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)       | 22 Sep 2020 16:36:27 |



US3292103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 16:42:57 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Sep 2020 16:36:27 |

US3292103

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:20:34

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:43:03 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 22 Sep 2020 16:36:32 |

US3292103

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:20:34

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'l'  | System           | 22 Sep 2020 16:36:32 |

**US3292103**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Was Contact Attempted?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:45:08 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 29 Sep 2020 16:04:11 |

**US3292103**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 10 Mar 2021 16:45:08 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '29 Sep 2020' | (b) (4), (b) (6)       | 29 Sep 2020 16:04:11 |

**US3292103**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.                        | (b) (4), (b) (6)       | 10 Mar 2021 16:45:08 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)       | 29 Sep 2020 16:04:11 |

US3292103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 16:45:08 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Sep 2020 16:04:11 |

US3292103

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:20:34

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:45:19 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 29 Sep 2020 16:04:15 |



**US3292103**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'l'  | System           | 29 Sep 2020 16:04:15 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:45:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 06 Oct 2020 16:33:45 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 16:45:57 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:09 |
| User entered '6 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 06 Oct 2020 16:33:45 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[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 14:20:53 |
| DataPoint Verified.            | (b) (4), (b) (6)            | 10 Mar 2021 16:45:57 |
| User signature succeeded.      | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:09 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 06 Oct 2020 16:33:45 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'VISIT3' | System           | 06 Oct 2020 16:33:45 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:46:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 06 Oct 2020 16:35:51 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 16:46:23 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:09 |
| User entered '6 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 06 Oct 2020 16:35:51 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

**Time of assessment (00:00-23:59)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:46:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '10:27'      | (b) (4), (b) (6)       | 06 Oct 2020 16:35:51 |



**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered '6 Oct 2020 10:27' | System           | 06 Oct 2020 16:35:51 |

US3292103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:46:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '36.3' C     | (b) (4), (b) (6)       | 06 Oct 2020 16:35:51 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Route of measurement](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 10 Mar 2021 16:46:23 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6)       | 06 Oct 2020 16:35:51 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:46:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 06 Oct 2020 16:35:51 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Pulse \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:46:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '70'         | (b) (4), (b) (6)       | 06 Oct 2020 16:35:51 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'bpm' | System           | 06 Oct 2020 16:35:51 |

US3292103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:46:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '12'         | (b) (4), (b) (6)       | 06 Oct 2020 16:35:51 |

US3292103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'breaths/min' | System           | 06 Oct 2020 16:35:51 |



**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:46:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '132'        | (b) (4), (b) (6)       | 06 Oct 2020 16:35:51 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'mmHg' | System           | 06 Oct 2020 16:35:51 |

US3292103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Diastolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:46:23 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '77'         | (b) (4), (b) (6)       | 06 Oct 2020 16:35:51 |

US3292103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'mmHg' | System           | 06 Oct 2020 16:35:51 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |

US3292103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:20:34

[Was the physical examination performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:48:05 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 06 Oct 2020 16:35:59 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:20:34**

**Date of examination (dd MMM yyyy)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:48:05 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered empty.       | (b) (4), (b) (6)       | 06 Oct 2020 16:35:59 |



US3292103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:49:55 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 06 Oct 2020 21:47:17 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:20:34**

**Collection date** (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:49:55 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '6 Oct 2020' | (b) (4), (b) (6)       | 06 Oct 2020 21:47:17 |

US3292103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

Collection time (00:00-23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:49:55 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered '10:40'      | (b) (4), (b) (6)       | 06 Oct 2020 21:47:17 |

US3292103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered '6 Oct 2020 10:40' | System           | 06 Oct 2020 21:47:17 |

**US3292103**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:50:27 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:09 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 06 Oct 2020 16:37:14 |

US3292103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:20:34

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'I'  | System           | 06 Oct 2020 16:37:14 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 64' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-08T11:48:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '44c540a7-7cfe-4c62-83b5-9dd079dc03b1' | System           | 08 Oct 2020 16:49:09 |
| User entered 'No (N)'  | System           | 08 Oct 2020 16:49:09 |



US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-08T11:48:59', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '44c540a7-7cfe-4c62-83b5-9dd079dc03b1' | System           | 08 Oct 2020 16:49:09 |
| User entered 'No (N)'  | System           | 08 Oct 2020 16:49:09 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-08T11:49:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '44c540a7-7cfe-4c62-83b5-9dd079dc03b1' User entered '08 Oct 2020 11:49:07' | System           | 08 Oct 2020 16:49:09 |
|  | System           | 08 Oct 2020 16:49:09 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.               | System           | 08 Aug 2020 23:39:00 |
| User entered '08 Oct 2020 00:01' | System           | 08 Aug 2020 23:39:00 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.               | System           | 08 Aug 2020 23:39:00 |
| User entered '12 Oct 2020 23:59' | System           | 08 Aug 2020 23:39:00 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 71' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-15T14:00:10', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e541bc98-bdc7-45a7-97e7-89f9e659b405' | System           | 15 Oct 2020 19:00:40 |
| User entered 'No (N)'  | System           | 15 Oct 2020 19:00:40 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-15T14:00:16', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e541bc98-bdc7-45a7-97e7-89f9e659b405' | System           | 15 Oct 2020 19:00:40 |
| User entered 'No (N)'  | System           | 15 Oct 2020 19:00:40 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-15T14:00:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'e541bc98-bdc7-45a7-97e7-89f9e659b405' User entered '15 Oct 2020 14:00:21' | System           | 15 Oct 2020 19:00:40 |
|  | System           | 15 Oct 2020 19:00:40 |



**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.               | System           | 08 Aug 2020 23:39:00 |
| User entered '15 Oct 2020 00:01' | System           | 08 Aug 2020 23:39:00 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.               | System           | 08 Aug 2020 23:39:00 |
| User entered '19 Oct 2020 23:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 78' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-22T13:36:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'fd5f2b16-fb73-4b3d-8a69-995dc5d21d52' | System           | 22 Oct 2020 18:38:02 |
| User entered 'No (N)'  | System           | 22 Oct 2020 18:38:02 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-22T13:36:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'fd5f2b16-fb73-4b3d-8a69-995dc5d21d52' | System           | 22 Oct 2020 18:38:02 |
| User entered 'No (N)'  | System           | 22 Oct 2020 18:38:02 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-10-22T13:37:05', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'fd5f2b16-fb73-4b3d-8a69-995dc5d21d52' User entered '22 Oct 2020 13:37:05' | System           | 22 Oct 2020 18:38:02 |
|  | System           | 22 Oct 2020 18:38:02 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.               | System           | 08 Aug 2020 23:39:00 |
| User entered '22 Oct 2020 00:01' | System           | 08 Aug 2020 23:39:00 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.               | System           | 08 Aug 2020 23:39:00 |
| User entered '26 Oct 2020 23:59' | System           | 08 Aug 2020 23:39:00 |



US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 92' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-06T12:12:19', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '34ab9771-67ed-480b-9615-a31a3ed06c9d' User entered 'No (N)' | System           | 06 Nov 2020 20:12:42 |
|  | System           | 06 Nov 2020 20:12:42 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-06T12:12:29', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '34ab9771-67ed-480b-9615-a31a3ed06c9d' | System           | 06 Nov 2020 20:12:42 |
| User entered 'No (N)'  | System           | 06 Nov 2020 20:12:42 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-06T12:12:36', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '34ab9771-67ed-480b-9615-a31a3ed06c9d' User entered '06 Nov 2020 12:12:36' | System           | 06 Nov 2020 20:12:42 |
|  | System           | 06 Nov 2020 20:12:42 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.               | System           | 08 Aug 2020 23:39:00 |
| User entered '05 Nov 2020 00:01' | System           | 08 Aug 2020 23:39:00 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.               | System           | 08 Aug 2020 23:39:00 |
| User entered '09 Nov 2020 23:59' | System           | 08 Aug 2020 23:39:00 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.    | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 99' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-12T17:40:40', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0fbca193-f4d6-41a6-af77-bacf456164e2' | System           | 13 Nov 2020 01:40:54 |
| User entered 'No (N)'  | System           | 13 Nov 2020 01:40:54 |



US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-12T17:40:45', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0fbca193-f4d6-41a6-af77-bacf456164e2' | System           | 13 Nov 2020 01:40:54 |
| User entered 'No (N)'  | System           | 13 Nov 2020 01:40:54 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-12T17:40:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '0fbca193-f4d6-41a6-af77-bacf456164e2' | System           | 13 Nov 2020 01:40:54 |
| User entered '12 Nov 2020 17:40:52'  | System           | 13 Nov 2020 01:40:54 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.               | System           | 08 Aug 2020 23:39:00 |
| User entered '12 Nov 2020 00:01' | System           | 08 Aug 2020 23:39:00 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 04 Mar 2021 23:51:25 |
| Data entry locked.               | System           | 08 Aug 2020 23:39:00 |
| User entered '16 Nov 2020 23:59' | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |
| Data entry locked.                        | System           | 08 Aug 2020 23:39:00 |
| User entered 'Day 106'                    | System           | 08 Aug 2020 23:39:00 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |



US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Chills](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Cough](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Shortness of breath](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Difficulty breathing](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Fatigue](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Muscle aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Body aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Headache](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[New loss of taste](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[New loss of smell](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Sore throat](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Congestion](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Runny nose](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Nausea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Vomiting](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Diarrhea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

US3292103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |
| Data entry locked.                        | System           | 08 Aug 2020 23:39:00 |
| User entered '19 Nov 2020 00:01'          | System           | 08 Aug 2020 23:39:00 |

**US3292103**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 16:46:46 |
| Data entry locked.                        | System           | 08 Aug 2020 23:39:00 |
| User entered '23 Nov 2020 23:59'          | System           | 08 Aug 2020 23:39:00 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-19T17:35:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '999b04c3-53b7-459d-a8ff-c15ac8665d1b' User entered 'Yes (Y)' | System | 19 Nov 2020 23:36:35 |
|   | System | 19 Nov 2020 23:36:35 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-19T17:36:04', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '999b04c3-53b7-459d-a8ff-c15ac8665d1b' User entered 'No (N)' | System | 19 Nov 2020 23:36:35 |
|  | System | 19 Nov 2020 23:36:35 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-19T17:36:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '999b04c3-53b7-459d-a8ff-c15ac8665d1b' User entered 'No (N)' | System | 19 Nov 2020 23:36:35 |
|  | System | 19 Nov 2020 23:36:35 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-19T17:35:53', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '999b04c3-53b7-459d-a8ff-c15ac8665d1b' User entered 'Yes (Y)' | System | 19 Nov 2020 23:36:35 |
|   | System | 19 Nov 2020 23:36:35 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-19T17:36:12', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '999b04c3-53b7-459d-a8ff-c15ac8665d1b' | System | 19 Nov 2020 23:36:35 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 19 Nov 2020 23:36:35 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-19T17:36:24', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '999b04c3-53b7-459d-a8ff-c15ac8665d1b' User entered '19 Nov 2020 17:36:24' | System | 19 Nov 2020 23:36:35 |
|  | System | 19 Nov 2020 23:36:35 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '16 Nov 2020 00:01' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '20 Nov 2020 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-23T10:32:41', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'dba4b2dd-453d-43c8-9607-332d6653ffa0' User entered 'No (N)' | System | 23 Nov 2020 16:32:58 |
|  | System | 23 Nov 2020 16:32:58 |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-23T10:32:47', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'dba4b2dd-453d-43c8-9607-332d6653ffa0' User entered 'No (N)' | System | 23 Nov 2020 16:32:58 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-11-23T10:32:55', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'dba4b2dd-453d-43c8-9607-332d6653ffa0' User entered '23 Nov 2020 10:32:55' | System | 23 Nov 2020 16:32:58 |
|  | System | 23 Nov 2020 16:32:58 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '23 Nov 2020 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '27 Nov 2020 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-01T14:26:38', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '15934ea9-458f-4ec9-aade-17ee51b413c9' User entered 'No (N)' | System | 01 Dec 2020 20:26:48 |
|  | System | 01 Dec 2020 20:26:48 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-01T14:26:43', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '15934ea9-458f-4ec9-aade-17ee51b413c9' | System | 01 Dec 2020 20:26:48 |
| User entered 'No (N)'  | System | 01 Dec 2020 20:26:48 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-01T14:26:46', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '15934ea9-458f-4ec9-aade-17ee51b413c9' User entered '01 Dec 2020 14:26:46' | System | 01 Dec 2020 20:26:48 |
|  | System | 01 Dec 2020 20:26:48 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '30 Nov 2020 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '04 Dec 2020 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-07T17:42:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'f7e1b25e-481f-4930-97e0-d980db1ca066' | System | 07 Dec 2020 23:43:10 |
| User entered 'No (N)'  | System | 07 Dec 2020 23:43:10 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-07T17:43:02', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'f7e1b25e-481f-4930-97e0-d980db1ca066' | System | 07 Dec 2020 23:43:10 |
| User entered 'No (N)'  | System | 07 Dec 2020 23:43:10 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-07T17:43:06', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'f7e1b25e-481f-4930-97e0-d980db1ca066' User entered '07 Dec 2020 17:43:06' | System | 07 Dec 2020 23:43:10 |
|  | System | 07 Dec 2020 23:43:10 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '07 Dec 2020 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '11 Dec 2020 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-14T21:41:25', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ec0b1761-10b2-4e39-aaa5-1d7ace058357' User entered 'No (N)' | System | 15 Dec 2020 03:41:41 |
|  | System | 15 Dec 2020 03:41:41 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-14T21:41:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ec0b1761-10b2-4e39-aaa5-1d7ace058357' | System | 15 Dec 2020 03:41:41 |
| User entered 'No (N)'  | System | 15 Dec 2020 03:41:41 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-14T21:41:35', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ec0b1761-10b2-4e39-aaa5-1d7ace058357' User entered '14 Dec 2020 21:41:35' | System | 15 Dec 2020 03:41:41 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '14 Dec 2020 00:01' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '18 Dec 2020 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-21T09:39:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '26c9a325-48ba-41c0-8c82-384da986502d' User entered 'No (N)' | System | 21 Dec 2020 15:40:11 |
|  | System | 21 Dec 2020 15:40:11 |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-21T09:40:04', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '26c9a325-48ba-41c0-8c82-384da986502d' User entered 'No (N)' | System | 21 Dec 2020 15:40:11 |
|  | System | 21 Dec 2020 15:40:11 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-21T09:40:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '26c9a325-48ba-41c0-8c82-384da986502d' User entered '21 Dec 2020 09:40:09' | System | 21 Dec 2020 15:40:11 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '21 Dec 2020 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '25 Dec 2020 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-28T10:33:54', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '29295c73-7f2c-4dd8-8128-9f906bd38f7c' User entered 'No (N)' | System | 28 Dec 2020 16:34:13 |
|  | System | 28 Dec 2020 16:34:13 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-28T10:34:02', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '29295c73-7f2c-4dd8-8128-9f906bd38f7c' User entered 'No (N)' | System | 28 Dec 2020 16:34:13 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2020-12-28T10:34:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '29295c73-7f2c-4dd8-8128-9f906bd38f7c' User entered '28 Dec 2020 10:34:09' | System | 28 Dec 2020 16:34:13 |
|  | System | 28 Dec 2020 16:34:13 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '28 Dec 2020 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '01 Jan 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-06T09:42:27', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8ffd4af4-fd24-4217-b1a0-cf17891f830a' User entered 'No (N)' | System | 06 Jan 2021 15:42:37 |
|  | System | 06 Jan 2021 15:42:37 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-06T09:42:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8ffd4af4-fd24-4217-b1a0-cf17891f830a' User entered 'No (N)' | System | 06 Jan 2021 15:42:37 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-06T09:42:34', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '8ffd4af4-fd24-4217-b1a0-cf17891f830a' User entered '06 Jan 2021 09:42:34' | System | 06 Jan 2021 15:42:37 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '04 Jan 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '08 Jan 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-13T10:17:57', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '59d3aadb-8056-4088-95d3-4fd0e830f9f7' | System | 13 Jan 2021 16:18:13 |
| User entered 'No (N)'  | System | 13 Jan 2021 16:18:13 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-13T10:18:05', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '59d3aadb-8056-4088-95d3-4fd0e830f9f7' | System | 13 Jan 2021 16:18:13 |
| User entered 'No (N)'  | System | 13 Jan 2021 16:18:13 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-13T10:18:09', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '59d3aadb-8056-4088-95d3-4fd0e830f9f7' | System | 13 Jan 2021 16:18:13 |
| User entered '13 Jan 2021 10:18:09'  | System | 13 Jan 2021 16:18:13 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '11 Jan 2021 00:01' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '15 Jan 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-20T12:24:58', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bca5cba7-2393-45bd-a925-7c29607c6fbc' User entered 'No (N)' | System | 20 Jan 2021 18:25:10 |
|  | System | 20 Jan 2021 18:25:10 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-20T12:25:04', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bca5cba7-2393-45bd-a925-7c29607c6fbc' User entered 'No (N)' | System | 20 Jan 2021 18:25:10 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-20T12:25:07', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bca5cba7-2393-45bd-a925-7c29607c6fbc' User entered '20 Jan 2021 12:25:07' | System | 20 Jan 2021 18:25:10 |
|  | System | 20 Jan 2021 18:25:10 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '18 Jan 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '22 Jan 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-27T10:04:16', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '4f087150-2f89-4295-94a7-fbf64409d28c' User entered 'Yes (Y)' | System | 27 Jan 2021 16:05:08 |
|   | System | 27 Jan 2021 16:05:08 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-27T10:04:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '4f087150-2f89-4295-94a7-fbf64409d28c' User entered 'No (N)' | System | 27 Jan 2021 16:05:08 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-27T10:04:31', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '4f087150-2f89-4295-94a7-fbf64409d28c' User entered 'No (N)' | System | 27 Jan 2021 16:05:08 |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-27T10:04:42', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '4f087150-2f89-4295-94a7-fbf64409d28c' User entered 'Yes (Y)' | System | 27 Jan 2021 16:05:08 |
|   | System | 27 Jan 2021 16:05:08 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-27T10:04:52', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '4f087150-2f89-4295-94a7-fbf64409d28c' | System | 27 Jan 2021 16:05:08 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 27 Jan 2021 16:05:08 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-01-27T10:04:56', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '4f087150-2f89-4295-94a7-fbf64409d28c' User entered '27 Jan 2021 10:04:56' | System | 27 Jan 2021 16:05:08 |
|  | System | 27 Jan 2021 16:05:08 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '25 Jan 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '29 Jan 2021 23:59' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-03T09:49:50', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2cf77340-1ef0-4606-8d1d-dbb75d3a9437' User entered 'No (N)' | System | 03 Feb 2021 15:50:04 |
|  | System | 03 Feb 2021 15:50:04 |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-03T09:49:54', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2cf77340-1ef0-4606-8d1d-dbb75d3a9437' User entered 'No (N)' | System | 03 Feb 2021 15:50:04 |
|  | System | 03 Feb 2021 15:50:04 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-03T09:50:01', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '2cf77340-1ef0-4606-8d1d-dbb75d3a9437' User entered '03 Feb 2021 09:50:01' | System | 03 Feb 2021 15:50:04 |
|  | System | 03 Feb 2021 15:50:04 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '01 Feb 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '05 Feb 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-10T12:00:18', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bdb70c86-91bd-4fa7-bfd8-f66d9e720989' | System | 10 Feb 2021 18:01:10 |
| User entered 'No (N)'  | System | 10 Feb 2021 18:01:10 |



US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-10T12:00:23', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bdb70c86-91bd-4fa7-bfd8-f66d9e720989' User entered 'No (N)' | System | 10 Feb 2021 18:01:10 |
|  | System | 10 Feb 2021 18:01:10 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-10T12:00:30', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'bdb70c86-91bd-4fa7-bfd8-f66d9e720989' User entered '10 Feb 2021 12:00:30' | System | 10 Feb 2021 18:01:10 |
|  | System | 10 Feb 2021 18:01:10 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '08 Feb 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '12 Feb 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-18T18:06:21', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'cd62568e-6367-40f7-8df3-9bee22df4cd4' User entered 'No (N)' | System | 19 Feb 2021 00:11:28 |
|  | System | 19 Feb 2021 00:11:28 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-18T18:06:26', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'cd62568e-6367-40f7-8df3-9bee22df4cd4' | System | 19 Feb 2021 00:11:28 |
| User entered 'No (N)'  | System | 19 Feb 2021 00:11:28 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-18T18:06:30', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'cd62568e-6367-40f7-8df3-9bee22df4cd4' | System | 19 Feb 2021 00:11:28 |
| User entered '18 Feb 2021 18:06:30'  | System | 19 Feb 2021 00:11:28 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '15 Feb 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '19 Feb 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-24T11:18:06-06:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9e6ff54f-e272-4e82-acd5-82067718e0b0' User entered 'No (N)' | System | 24 Feb 2021 17:23:30 |
|  | System | 24 Feb 2021 17:23:30 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-24T11:18:11-06:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9e6ff54f-e272-4e82-acd5-82067718e0b0' User entered 'No (N)' | System | 24 Feb 2021 17:23:30 |
|  | System | 24 Feb 2021 17:23:30 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-24T11:18:15-06:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '9e6ff54f-e272-4e82-acd5-82067718e0b0' | System | 24 Feb 2021 17:23:30 |
| User entered '24 Feb 2021 17:18:15'  | System | 24 Feb 2021 17:23:30 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '22 Feb 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '26 Feb 2021 23:59' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-03T12:02:48-06:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7e0d9801-a896-47e7-9054-355fe3a185fa' User entered 'No (N)' | System | 11 Mar 2021 18:16:42 |
|  | System | 11 Mar 2021 18:16:42 |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-03T12:02:56-06:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7e0d9801-a896-47e7-9054-355fe3a185fa' User entered 'No (N)' | System | 11 Mar 2021 18:16:42 |
|  | System | 11 Mar 2021 18:16:42 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-03T12:03:00-06:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '7e0d9801-a896-47e7-9054-355fe3a185fa' User entered '03 Mar 2021 12:03:00' | System | 11 Mar 2021 18:16:42 |
|  | System | 11 Mar 2021 18:16:42 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '01 Mar 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '05 Mar 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-11T12:16:48-06:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '21534a48-328d-4799-9555-44bdcbe7da6a' | System | 11 Mar 2021 18:17:01 |
| User entered 'No (N)'  | System | 11 Mar 2021 18:17:01 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-11T12:16:54-06:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '21534a48-328d-4799-9555-44bdcbe7da6a' | System | 11 Mar 2021 18:17:01 |
| User entered 'No (N)'  | System | 11 Mar 2021 18:17:01 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-11T12:16:57-06:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '21534a48-328d-4799-9555-44bdcbe7da6a' User entered '11 Mar 2021 12:16:57' | System | 11 Mar 2021 18:17:01 |
|  | System | 11 Mar 2021 18:17:01 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '08 Mar 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '12 Mar 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-17T12:13:53-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c678af7c-fc2c-473f-9bcf-ff9064a2a1b6' | System | 17 Mar 2021 17:14:08 |
| User entered 'No (N)'  | System | 17 Mar 2021 17:14:08 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-17T12:14:00-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c678af7c-fc2c-473f-9bcf-ff9064a2a1b6' | System | 17 Mar 2021 17:14:08 |
| User entered 'No (N)'  | System | 17 Mar 2021 17:14:08 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-17T12:14:04-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'c678af7c-fc2c-473f-9bcf-ff9064a2a1b6' | System | 17 Mar 2021 17:14:08 |
| User entered '17 Mar 2021 12:14:04'  | System | 17 Mar 2021 17:14:08 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '15 Mar 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '19 Mar 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-25T14:03:09-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10c4f5a8-9fec-4718-adcd-d09098ef0a9b' User entered 'No (N)' | System | 25 Mar 2021 19:04:59 |
|  | System | 25 Mar 2021 19:04:59 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-25T14:03:13-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10c4f5a8-9fec-4718-adcd-d09098ef0a9b' | System | 25 Mar 2021 19:04:59 |
| User entered 'No (N)'  | System | 25 Mar 2021 19:04:59 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-25T14:03:16-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '10c4f5a8-9fec-4718-adcd-d09098ef0a9b' | System | 25 Mar 2021 19:04:59 |
| User entered '25 Mar 2021 14:03:16'  | System | 25 Mar 2021 19:04:59 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '22 Mar 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '26 Mar 2021 23:59' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-31T12:00:58-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '66f09a63-90c0-4626-b9c5-7f642be0ee47' | System | 31 Mar 2021 17:02:20 |
| User entered 'No (N)'  | System | 31 Mar 2021 17:02:20 |

US3292103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:20:34

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-31T12:01:04-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '66f09a63-90c0-4626-b9c5-7f642be0ee47' | System | 31 Mar 2021 17:02:20 |
| User entered 'No (N)'  | System | 31 Mar 2021 17:02:20 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-03-31T12:01:07-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '66f09a63-90c0-4626-b9c5-7f642be0ee47' | System | 31 Mar 2021 17:02:20 |
| User entered '31 Mar 2021 12:01:07'  | System | 31 Mar 2021 17:02:20 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '29 Mar 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '02 Apr 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-04-08T08:41:42-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '24f5535e-fa60-4987-9c8a-20a2343410fe' User entered 'No (N)' | System | 08 Apr 2021 13:41:58 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-04-08T08:41:50-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '24f5535e-fa60-4987-9c8a-20a2343410fe' User entered 'No (N)' | System | 08 Apr 2021 13:41:58 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-04-08T08:41:55-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '24f5535e-fa60-4987-9c8a-20a2343410fe' | System | 08 Apr 2021 13:41:58 |
| User entered '08 Apr 2021 08:41:55'  | System | 08 Apr 2021 13:41:58 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '05 Apr 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '09 Apr 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-04-15T08:17:55-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'eb4fee32-b29b-460c-a8ae-7f1588df291b' User entered 'No (N)' | System | 15 Apr 2021 13:18:09 |
|  | System | 15 Apr 2021 13:18:09 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-04-15T08:18:04-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'eb4fee32-b29b-460c-a8ae-7f1588df291b' | System | 15 Apr 2021 13:18:09 |
| User entered 'No (N)'  | System | 15 Apr 2021 13:18:09 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-04-15T08:18:07-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'eb4fee32-b29b-460c-a8ae-7f1588df291b' User entered '15 Apr 2021 08:18:07' | System | 15 Apr 2021 13:18:09 |
|  | System | 15 Apr 2021 13:18:09 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '12 Apr 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '16 Apr 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-04-22T10:36:31-07:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ea67c1fb-ad1a-45ee-9bf4-50fae2ba4bba' User entered 'No (N)' | System | 22 Apr 2021 17:36:55 |
|  | System | 22 Apr 2021 17:36:55 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-04-22T10:36:43-07:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ea67c1fb-ad1a-45ee-9bf4-50fae2ba4bba' User entered 'No (N)' | System | 22 Apr 2021 17:36:55 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-04-22T10:36:51-07:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'ea67c1fb-ad1a-45ee-9bf4-50fae2ba4bba' User entered '22 Apr 2021 10:36:51' | System | 22 Apr 2021 17:36:55 |
|  | System | 22 Apr 2021 17:36:55 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '19 Apr 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '23 Apr 2021 23:59' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-04-29T12:16:23-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '64ea2e11-c522-4d2e-a23f-35c5e0de827e' User entered 'No (N)' | System | 29 Apr 2021 17:16:41 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-04-29T12:16:34-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '64ea2e11-c522-4d2e-a23f-35c5e0de827e' User entered 'No (N)' | System | 29 Apr 2021 17:16:41 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-04-29T12:16:37-05:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: '64ea2e11-c522-4d2e-a23f-35c5e0de827e' User entered '29 Apr 2021 12:16:37' | System | 29 Apr 2021 17:16:41 |
|  | System | 29 Apr 2021 17:16:41 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '26 Apr 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '30 Apr 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '03 May 2021 00:01' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '07 May 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '10 May 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '14 May 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '17 May 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '21 May 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '24 May 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '28 May 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '31 May 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '04 Jun 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '07 Jun 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '11 Jun 2021 23:59' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '14 Jun 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '18 Jun 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '21 Jun 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '25 Jun 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '28 Jun 2021 00:01' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '02 Jul 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '05 Jul 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '09 Jul 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '12 Jul 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '16 Jul 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '19 Jul 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '23 Jul 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '26 Jul 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '30 Jul 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '02 Aug 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '06 Aug 2021 23:59' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '09 Aug 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '13 Aug 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '16 Aug 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '20 Aug 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '23 Aug 2021 00:01' | System | 19 Nov 2020 16:46:46 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '27 Aug 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '30 Aug 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '03 Sep 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '06 Sep 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '10 Sep 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '13 Sep 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '17 Sep 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '20 Sep 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '24 Sep 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '27 Sep 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '01 Oct 2021 23:59' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '04 Oct 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '08 Oct 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '11 Oct 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '15 Oct 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '18 Oct 2021 00:01' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '22 Oct 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '25 Oct 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '29 Oct 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '01 Nov 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '05 Nov 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '08 Nov 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '12 Nov 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '15 Nov 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '19 Nov 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '22 Nov 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '26 Nov 2021 23:59' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '29 Nov 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '03 Dec 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '06 Dec 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '10 Dec 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '13 Dec 2021 00:01' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '17 Dec 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '20 Dec 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '24 Dec 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '27 Dec 2021 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '31 Dec 2021 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 16:46:46 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '03 Jan 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '07 Jan 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '10 Jan 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '14 Jan 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '17 Jan 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '21 Jan 2022 23:59' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '24 Jan 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '28 Jan 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '31 Jan 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '04 Feb 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '07 Feb 2022 00:01' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '11 Feb 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '14 Feb 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '18 Feb 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '21 Feb 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '25 Feb 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 16:46:46 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '28 Feb 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '04 Mar 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '07 Mar 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '11 Mar 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 16:46:46 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '14 Mar 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '18 Mar 2022 23:59' | System | 19 Nov 2020 16:46:46 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 16:46:46 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '21 Mar 2022 00:01' | System | 19 Nov 2020 16:46:46 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '25 Mar 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 16:46:46 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '28 Mar 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '01 Apr 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '04 Apr 2022 00:01' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '08 Apr 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '11 Apr 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '15 Apr 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '18 Apr 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '22 Apr 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 16:46:46 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '25 Apr 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '29 Apr 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '02 May 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '06 May 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '09 May 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '13 May 2022 23:59' | System | 19 Nov 2020 16:46:46 |



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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '16 May 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '20 May 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '23 May 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '27 May 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '30 May 2022 00:01' | System | 19 Nov 2020 16:46:46 |



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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '03 Jun 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 16:46:46 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '06 Jun 2022 00:01' | System | 19 Nov 2020 16:46:46 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '10 Jun 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '13 Jun 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '17 Jun 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '20 Jun 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '24 Jun 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '27 Jun 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '01 Jul 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '04 Jul 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '08 Jul 2022 23:59' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '11 Jul 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '15 Jul 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '18 Jul 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '22 Jul 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '25 Jul 2022 00:01' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '29 Jul 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '01 Aug 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '05 Aug 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '08 Aug 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '12 Aug 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '15 Aug 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '19 Aug 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '22 Aug 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '26 Aug 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '29 Aug 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '02 Sep 2022 23:59' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '05 Sep 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '09 Sep 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '12 Sep 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '16 Sep 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '19 Sep 2022 00:01' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '23 Sep 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '26 Sep 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '30 Sep 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '03 Oct 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '07 Oct 2022 23:59' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 16:46:46 |



**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '10 Oct 2022 00:01' | System | 19 Nov 2020 16:46:46 |

**US3292103**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:20:34**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 16:46:46 |
| Amendment Manager: User entered '14 Oct 2022 23:59' | System | 19 Nov 2020 16:46:46 |

US3292103

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:20:34

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-28T10:44:53-06:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd609ac8b-ed0d-4c79-861a-f8d459612b68' | System           | 28 Feb 2021 16:45:06 |
| User entered 'No (N)'  | System           | 28 Feb 2021 16:45:06 |

**US3292103**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Date & Time of Submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 09:30:30 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46EBB0B1-3FE3-4933-B635-5F9B5EA50CB1)', Time: '2021-02-28T10:45:02-06:00', User OID: 'PatientReportedOutcome (US3292103)', ODM File OID: 'd609ac8b-ed0d-4c79-861a-f8d459612b68' User entered '28 Feb 2021 10:45:02' | System           | 28 Feb 2021 16:45:06 |
|  | System           | 28 Feb 2021 16:45:06 |

**US3292103**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Was Contact Attempted?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:53:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 30 Oct 2020 19:43:56 |

**US3292103**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 10 Mar 2021 16:53:33 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '30 Oct 2020' | (b) (4), (b) (6)       | 30 Oct 2020 19:43:56 |

US3292103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Please select one status for the follow-up contact](#)

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.                        | (b) (4), (b) (6)       | 10 Mar 2021 16:53:33 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)       | 30 Oct 2020 19:43:56 |

US3292103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       |                  | 10 Mar 2021 16:53:33 |
| User signature succeeded. | (b) (4)          | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4), (b) (6) | 30 Oct 2020 19:43:56 |



**US3292103**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 14 Apr 2021 14:20:53 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:53:45 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 30 Oct 2020 19:43:59 |

**US3292103**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 14:20:53 |
| User entered 'l'  | System           | 30 Oct 2020 19:43:59 |

**US3292103**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Was Contact Attempted?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 24 Apr 2021 12:37:26 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:54:16 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 07 Dec 2020 17:24:19 |

**US3292103**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 12:37:26 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 16:54:16 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered '4 Dec 2020' | (b) (4)<br>(b) (4), (b) (6) | 07 Dec 2020 17:24:19 |

**US3292103**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 24 Apr 2021 12:37:26 |
| DataPoint Verified.                        | (b) (4), (b) (6)       | 10 Mar 2021 16:54:16 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)       | 07 Dec 2020 17:24:19 |

US3292103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 12:37:26 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 16:54:16 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Dec 2020 17:24:19 |

**US3292103**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 12:37:26 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 16:54:31 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Dec 2020 17:24:23 |

**US3292103**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:37:26 |
| User entered 'l'  | System           | 07 Dec 2020 17:24:23 |



**US3292103**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Was Contact Attempted?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 24 Apr 2021 12:37:26 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:56:59 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 27 Jan 2021 20:16:56 |

**US3292103**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 24 Apr 2021 12:37:26 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:56:59 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:07 |
| User entered '3 Jan 2021' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 27 Jan 2021 20:16:56 |

**US3292103**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                           | 24 Apr 2021 12:37:26 |
| DataPoint Verified.                        | (b) (4), (b) (6)                           | 10 Mar 2021 16:56:59 |
| User signature succeeded.                  | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 27 Jan 2021 20:16:56 |

US3292103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 24 Apr 2021 12:37:26 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:56:59 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 27 Jan 2021 20:16:56 |

US3292103

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:20:34

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 24 Apr 2021 12:37:26 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 10 Mar 2021 16:57:08 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 27 Jan 2021 20:17:01 |

**US3292103**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:37:26 |
| User entered 'l'  | System           | 27 Jan 2021 20:17:01 |

**US3292103**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Was Contact Attempted?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 24 Apr 2021 12:37:26 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 16:58:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 03 Feb 2021 17:41:23 |

**US3292103**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 12:37:26 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 16:58:57 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered '2 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 03 Feb 2021 17:41:23 |



**US3292103**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 24 Apr 2021 12:37:26 |
| DataPoint Verified.                        | (b) (4), (b) (6)       | 10 Mar 2021 16:58:57 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)       | 03 Feb 2021 17:41:23 |

US3292103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:20:34

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 12:37:26 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 16:58:57 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 03 Feb 2021 17:41:23 |

**US3292103**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 24 Apr 2021 12:37:26 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 16:59:32 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 03 Feb 2021 17:41:38 |

**US3292103**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:37:26 |
| User entered 'l'  | System           | 03 Feb 2021 17:41:38 |

**US3292103**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 30 Mar 2021 18:47:41 |

**US3292103**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered '1 Mar 2021' | (b) (4), (b) (6)       | 30 Mar 2021 18:47:41 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:20:34

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded.      | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6)       | 30 Mar 2021 18:47:41 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:20:34

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 27 Apr 2021 13:34:29 |
| User entered 'VISIT4' | System           | 30 Mar 2021 18:47:41 |



US3292103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 30 Mar 2021 18:47:56 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered empty.       | (b) (4), (b) (6)       | 30 Mar 2021 18:47:56 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Time of assessment (00:00-23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered empty.       | (b) (4), (b) (6)       | 30 Mar 2021 18:47:56 |

**US3292103**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:34:29 |
| User entered empty. | System           | 30 Mar 2021 18:47:56 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered empty.       | (b) (4), (b) (6)       | 30 Mar 2021 18:47:56 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

[Route of measurement](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered empty.       | (b) (4), (b) (6)       | 30 Mar 2021 18:47:56 |

**US3292103**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered empty.       | (b) (4), (b) (6)       | 30 Mar 2021 18:47:56 |

**US3292103**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Pulse \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered empty.       | (b) (4), (b) (6)       | 30 Mar 2021 18:47:56 |



**US3292103**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:34:29 |
| User entered empty. | System           | 30 Mar 2021 18:47:56 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered empty.       | (b) (4), (b) (6)       | 30 Mar 2021 18:47:56 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

[Respiratory Rate units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:34:29 |
| User entered empty. | System           | 30 Mar 2021 18:47:56 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Systolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered empty.       | (b) (4), (b) (6)       | 30 Mar 2021 18:47:56 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:34:29 |
| User entered empty. | System           | 30 Mar 2021 18:47:56 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Diastolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered empty.       | (b) (4), (b) (6)       | 30 Mar 2021 18:47:56 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 13:34:29 |
| User entered empty. | System           | 30 Mar 2021 18:47:56 |

**US3292103**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:34:29 |



US3292103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:34:29 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:20:34

[Was the physical examination performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 30 Mar 2021 18:48:00 |

**US3292103**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:20:34**

**Date of examination** (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered empty.       | (b) (4), (b) (6)       | 30 Mar 2021 18:48:00 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 30 Mar 2021 18:48:14 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

Collection date (dd MMM yyyy)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered '1 Mar 2021' | (b) (4), (b) (6)       | 30 Mar 2021 18:48:14 |

**US3292103**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:20:34**

**Collection time (00:00-23:59)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered '11:59'      | (b) (4), (b) (6)       | 30 Mar 2021 18:48:14 |

US3292103

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 27 Apr 2021 13:34:29 |
| User entered '1 Mar 2021 11:59' | System           | 30 Mar 2021 18:48:14 |

**US3292103**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 27 Apr 2021 13:34:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 30 Mar 2021 18:48:19 |



**US3292103**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 13:34:29 |
| User entered 'I'  | System           | 30 Mar 2021 18:48:19 |

**US3292103**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Was Contact Attempted?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 02 May 2021 05:07:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 05 Apr 2021 15:41:03 |

**US3292103**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 02 May 2021 05:07:18 |
| User signature succeeded.  | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered '31 Mar 2021' | (b) (4), (b) (6)       | 05 Apr 2021 15:41:03 |

**US3292103**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 02 May 2021 05:07:18 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)       | 05 Apr 2021 15:41:03 |

**US3292103**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:20:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 02 May 2021 05:07:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered empty.       | (b) (4), (b) (6)       | 05 Apr 2021 15:41:03 |

**US3292103**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 02 May 2021 05:07:18 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 05 Apr 2021 15:41:07 |

**US3292103**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:20:34**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 05:07:18 |
| User entered 'l'  | System           | 05 Apr 2021 15:41:07 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:20 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 17:00:11 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:47:21 |



**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 20:32:20 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 10 Mar 2021 17:00:11 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:47:21 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 28 Apr 2021 20:32:20 |
| DataPoint Verified.            | (b) (4), (b) (6)            | 10 Mar 2021 17:00:11 |
| User signature succeeded.      | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:47:21 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:20:34**

[Folder OID](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 20:32:20 |
| User entered 'UNBLND_DECIDE' | System           | 14 Jan 2021 18:47:21 |

US3292103

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:20:34

Date of updated informed consent (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 20:32:20 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 10 Mar 2021 17:04:53 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:48:00 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:20:34**

[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 20:32:20 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User entered '0' WR# 5295537               | (b) (4)                | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System                 | 06 Mar 2021 03:32:14 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:20:34**

[Was the participant unblinded?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:20 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 17:04:53 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:48:00 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:20:34**

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 20:32:20 |
| User signature succeeded.   | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| 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 03:32:14 |

US3292103

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:20:34

Date of unblinding (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 20:32:20 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 10 Mar 2021 17:04:53 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:48:00 |



US3292103

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:20:34

[Participant randomization assignment](#)

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)            | 28 Apr 2021 20:32:20 |
| DataPoint Verified.                  | (b) (4), (b) (6)            | 10 Mar 2021 17:04:53 |
| User signature succeeded.            | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:48:00 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:20:34**

[Actual Dose 1](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.                                       | (b) (4), (b) (6)       | 28 Apr 2021 20:32:20 |
| DataPoint Verified.                                     | (b) (4), (b) (6)       | 10 Mar 2021 17:04:53 |
| User signature succeeded.                               | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | (b) (4)<br>System      | 20 Jan 2021 01:35:02 |
| User entered 'mRNA-1273 (mRNA-1273)'                    | (b) (4), (b) (6)       | 14 Jan 2021 18:48:00 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:20:34**

[Actual Dose 2](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.                                       | (b) (4), (b) (6)                  | 28 Apr 2021 20:32:20 |
| DataPoint Verified.                                     | (b) (4), (b) (6)                  | 10 Mar 2021 17:04:53 |
| User signature succeeded.                               | Douglas Denham (b) (4)<br>(b) (4) | 22 Feb 2021 18:45:07 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | System                            | 20 Jan 2021 01:35:02 |
| User entered 'mRNA-1273 (mRNA-1273)'                    | (b) (4), (b) (6)                  | 14 Jan 2021 18:48:00 |

US3292103

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:20:34

[Will participant receive mRNA-1273?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:20 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 17:04:53 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:48:00 |

US3292103

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:20:34

[Placebo Only Flag](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 20:32:20 |
| User entered empty. | System           | 14 Jan 2021 18:48:00 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:20:34**

[Continuing with mRNA-1273](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 20:32:20 |
| User entered empty. | System           | 14 Jan 2021 18:48:00 |

US3292103

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:20 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 25 Mar 2021 20:14:52 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:48:37 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:20:34**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 20:32:20 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 25 Mar 2021 20:14:52 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:48:37 |



US3292103

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

Collection time (00:00-23:59)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 20:32:20 |
| User signature succeeded.  | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| User closed query 'Per source, collection time is 1419. ' (Site from CRA).             | (b) (4)                |                      |
| DataPoint Verified.  | (b) (4), (b) (6)       | 25 Mar 2021 20:15:00 |
|  | (b) (4), (b) (6)       | 25 Mar 2021 20:14:52 |
| Query 'Per source, collection time is 1419. ' answered with 'updated' (Site from CRA). | Dawn Killian (b) (4)   | 23 Mar 2021 18:28:49 |
| Signature has been broken.   | (b) (4)                |                      |
|  | Dawn Killian (b) (4)   | 23 Mar 2021 18:28:43 |
| User entered '14:19' reason for change: Data Entry Error                               | (b) (4)                |                      |
|  | Dawn Killian (b) (4)   | 23 Mar 2021 18:28:43 |
| User opened query 'Per source, collection time is 1419. ' (Site from CRA).             | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:06:27 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
|  | (b) (4)                |                      |
| User entered '14:49'   | (b) (4), (b) (6)       | 14 Jan 2021 18:48:37 |

US3292103

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:20:34

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 20:32:20 |
| User entered '12 Jan 2021 14:19' | System           | 23 Mar 2021 18:28:43 |
| User entered '12 Jan 2021 14:49' | System           | 14 Jan 2021 18:48:37 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:20:34**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:20 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 17:06:35 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:48:55 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:20:34**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 20:32:20 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 10 Mar 2021 17:06:35 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered '12 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:48:55 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:20:34**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 20:32:20 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 10 Mar 2021 17:06:35 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| User entered '14:35'      | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:48:55 |

**US3292103**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:20:34**

[Collection Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 20:32:20 |
| User entered '12 Jan 2021 14:35' | System           | 14 Jan 2021 18:48:55 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 16:20:34**

[Visit Date](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 17:41:27 |
| User signature succeeded.  | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 25 Mar 2021 20:07:23 |
| User entered '08 Aug 2020' | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:00 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 16:20:34**

[Physical Exam](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 17:41:27 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 25 Mar 2021 20:07:23 |
| User entered '0'          | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:00 |



US3292103

Folder: Unscheduled 08 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 16:20:34

[Vital Signs](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 17:41:27 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 25 Mar 2021 20:07:23 |
| User entered 'l'          | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:00 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Unscheduled Visit Assessment**

**Generated On: 09 Jun 2021 16:20:34**

[Immunogenicity Assessment](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 17:41:27 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 25 Mar 2021 20:07:23 |
| User entered '0'          | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:00 |

US3292103

Folder: Unscheduled 08 Aug 2020

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 16:20:34

[Pregnancy Test](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 17:41:27 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 25 Mar 2021 20:07:23 |
| User entered '0'          | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:00 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 17:41:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 25 Mar 2021 20:07:32 |
| User entered 'Yes (Y)'    | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:29 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 17:41:33 |
| User signature succeeded.  | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 25 Mar 2021 20:07:32 |
| User entered '08 Aug 2020' | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:29 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

**Time of assessment (00:00-23:59)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 17:41:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 25 Mar 2021 20:07:32 |
| User entered '16:10'      | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:29 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Apr 2021 17:41:33 |
| User entered '08 Aug 2020 16:10' | System           | 23 Mar 2021 18:22:29 |

US3292103

Folder: Unscheduled 08 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

Temperature (xxx.x)

| Audit                                    | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 25 Apr 2021 17:41:33 |
| User signature succeeded.                | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.                      | (b) (4), (b) (6)       | 25 Mar 2021 20:07:32 |
| User entered missing code ND - Not Done. | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:29 |



**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Route of measurement](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 17:41:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 25 Mar 2021 20:07:32 |
| User entered empty.       | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:29 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 17:41:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 25 Mar 2021 20:07:32 |
| User entered empty.       | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:29 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Pulse \(xxx\)](#)

| Audit                                    | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 25 Apr 2021 17:41:33 |
| User signature succeeded.                | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.                      | (b) (4), (b) (6)       | 25 Mar 2021 20:07:32 |
| User entered missing code ND - Not Done. | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:29 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 17:41:33 |
| User entered 'bpm' | System           | 23 Mar 2021 18:22:29 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Respiratory Rate \(xxx\)](#)

| Audit                                    | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 25 Apr 2021 17:41:33 |
| User signature succeeded.                | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.                      | (b) (4), (b) (6)       | 25 Mar 2021 20:07:32 |
| User entered missing code ND - Not Done. | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:29 |

US3292103

Folder: Unscheduled 08 Aug 2020

Form: Vital Signs

Generated On: 09 Jun 2021 16:20:34

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 25 Apr 2021 17:41:33 |
| User entered 'breaths/min' | System           | 23 Mar 2021 18:22:29 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 17:41:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 25 Mar 2021 20:07:32 |
| User entered '161'        | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:29 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 17:41:33 |
| User entered 'mmHg' | System           | 23 Mar 2021 18:22:29 |



**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 17:41:33 |
| User signature succeeded. | Douglas Denham (b) (4) | 08 Apr 2021 16:13:33 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 25 Mar 2021 20:07:32 |
| User entered '86'         | Dawn Killian (b) (4)   | 23 Mar 2021 18:22:29 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 17:41:33 |
| User entered 'mmHg' | System           | 23 Mar 2021 18:22:29 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 17:41:33 |

**US3292103**

**Folder: Unscheduled 08 Aug 2020**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:20:34**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 17:41:33 |

US3292103

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:20:34

[Did the participant experience any adverse events?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 03 May 2021 05:13:16 |
| DataPoint Verified.       | (b) (4), (b) (6)                     | 10 Mar 2021 17:07:58 |
| User signature succeeded. | Douglas Denham (b) (4)               | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Antonio Gutierrez (b) (4) | 20 Nov 2020 21:10:09 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[AEID](#)

| Audit                                 | User                   | Time (GMT)           |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded.             | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.                   | (b) (4)                | 18 Jan 2021 19:47:43 |
| Reviewed for Safety.                  | (b) (4), (b) (6)       | 23 Nov 2020 23:37:58 |
| User entered                          |                        | 23 Nov 2020 23:37:47 |
| 'USA-US072-2020-mRNA-1273-P301000013' |                        |                      |
| User entered 'New'                    |                        | 23 Nov 2020 23:37:47 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Adverse event](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 18 Jan 2021 19:47:43 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cerebral injuries NEC, PT: Subdural haematoma, LLT: Subdural hematoma - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 20 Nov 2020 21:52:05 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4) | 20 Nov 2020 21:52:05 |
| Data point term sent to Coder  | System                          | 20 Nov 2020 21:51:20 |
| User entered 'Subdural Hematoma'   | Antonio Gutierrez (b) (4)       | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Was this a medically-attended AE?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered 'Yes (Y)'    | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |



**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered 'No (N)'     | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered 'No (N)'     | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered '14 Nov 2020' | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered empty.       | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Ongoing?](#)

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| User signature succeeded.                                | Douglas Denham (b) (4)    | 16 Apr 2021 14:02:04 |
| DataPoint Verified.                                      | (b) (4)                   | 11 Mar 2021 21:13:34 |
| DataPoint Un-verified.                                   | (b) (4), (b) (6)          | 01 Feb 2021 18:02:50 |
| User entered 'No (N)' reason for change: New Information |                           | 01 Feb 2021 18:02:50 |
| DataPoint Verified.                                      |                           | 18 Jan 2021 19:47:43 |
| User entered 'Yes (Y)'                                   | Antonio Gutierrez (b) (4) | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, end date (dd MMM yyyy)

| Audit   | User                      | Time (GMT)           |
|---|---------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)    | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)                   | 11 Mar 2021 21:13:37 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'updated end date for AE 26 JAN 2021' (Site from Safety). User entered '26 Jan 2021' reason for change: New Information | (b) (4), (b) (6)          | 02 Feb 2021 17:20:01 |
| DataPoint Un-verified.  |                           | 01 Feb 2021 18:03:21 |
| DataPoint Verified.   |                           | 01 Feb 2021 18:02:50 |
|   |                           | 18 Jan 2021 19:47:46 |
|   |                           | 18 Jan 2021 19:47:43 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). User entered empty.  | Antonio Gutierrez (b) (4) | 30 Nov 2020 23:05:12 |
|   |                           | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

**End time (00:00-23:59)**

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)    | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                   |                      |
|                           | (b) (4), (b) (6)          | 11 Mar 2021 21:13:39 |
| DataPoint Un-verified.    | (b) (4), (b) (6)          | 18 Jan 2021 19:50:13 |
| DataPoint Verified.       | (b) (4), (b) (6)          | 18 Jan 2021 19:47:43 |
| User entered empty.       | Antonio Gutierrez (b) (4) | 20 Nov 2020 21:51:16 |



**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Severity](#)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
| User closed query 'PV Query: As event resulted in hospitalization, please confirm the intensity of grade 3. If not updated, please clarify. ' (Site from Safety).               | (b) (4)                    |                      |
| Query 'PV Query: As event resulted in hospitalization, please confirm the intensity of grade 3. If not updated, please clarify. ' answered with 'confirmed' (Site from Safety). | (b) (4), (b) (6)           | 20 Jan 2021 21:23:03 |
| DataPoint Verified.   | Victoria Hernandez (b) (4) | 19 Jan 2021 16:43:47 |
|   | (b) (4)                    |                      |
|   | (b) (4), (b) (6)           | 18 Jan 2021 19:47:43 |
| User opened query 'PV Query: As event resulted in hospitalization, please confirm the intensity of grade 3. If not updated, please clarify. ' (Site from Safety).               | (b) (4), (b) (6)           | 30 Nov 2020 23:04:28 |
| User entered 'Grade 3/Severe (Grade 3/Severe)'  | Antonio Gutierrez (b) (4)  | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Is the adverse event serious?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered 'Yes (Y)'    | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered '0'          | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered '0'          | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered 'I'          | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

Hospital Admission Date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered '15 Nov 2020' | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

Hospital Discharge Date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered '17 Nov 2020' | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |



**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Admitted to ICU?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered 'Yes (Y)'    | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered '3'          | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered '0'          | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered '0'          | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered '0'          | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Relationship to investigational product](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Relationship to Study Procedure](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered 'Not Related (NOT RELATED)' | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Action taken with investigational product](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.                            | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |



**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[None](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered '0'          | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Concomitant Medication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered 'l'          | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Concomitant Procedure](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
| User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).   | (b) (4), (b) (6)           | 25 Jan 2021 09:06:24 |
| Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'please advise on where to document Treatment procedures' (Site from DM). | Victoria Hernandez (b) (4) | 19 Jan 2021 16:49:08 |
| DataPoint Verified.  | (b) (4), (b) (6)           | 18 Jan 2021 19:49:30 |
| DataPoint Un-verified.   | (b) (4), (b) (6)           | 18 Jan 2021 19:49:17 |
| DataPoint Verified.  | (b) (4), (b) (6)           | 18 Jan 2021 19:47:43 |
| User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).   | (b) (4), (b) (6)           | 08 Dec 2020 05:58:43 |
| User entered 'I'   | Antonio Gutierrez (b) (4)  | 20 Nov 2020 21:51:16 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Outcome](#)

| Audit   | User                      | Time (GMT)           |
|---|---------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)    | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)                   | 11 Mar 2021 21:13:44 |
| User closed query '. PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).                          | (b) (4), (b) (6)          | 02 Feb 2021 17:19:58 |
| Query '. PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'AE has been REsolved' (Site from Safety). |                           | 01 Feb 2021 18:03:32 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information   |                           | 01 Feb 2021 18:02:50 |
| DataPoint Un-verified.  |                           | 18 Jan 2021 19:50:03 |
| DataPoint Verified.   |                           | 18 Jan 2021 19:47:43 |
| User opened query '. PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).                          |                           | 30 Nov 2020 23:04:45 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'  | Antonio Gutierrez (b) (4) | 20 Nov 2020 21:51:16 |

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:47:43 |
| User entered empty.       | Antonio Gutierrez (b) (4)   | 20 Nov 2020 21:51:16 |

US3292103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Narrative](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User closed query 'Per CDM: As per your response "Additional AE added" no update has been there in the corresponding AE eCRF, Please review and update accordingly, else clarify.' (Site from DM).  | (b) (4)                |                      |
| Query 'Per CDM: As per your response "Additional AE added" no update has been there in the corresponding AE eCRF, Please review and update accordingly, else clarify.' answered with 'updated AE' (Site from DM).   | (b) (4), (b) (6)       | 24 Mar 2021 11:26:56 |
| DataPoint Verified.   | Dawn Killian (b) (4)   | 23 Mar 2021 18:39:28 |
|   | (b) (4)                |                      |
|   | (b) (4), (b) (6)       | 10 Mar 2021 17:12:06 |
| User opened query 'Per CDM: As per your response "Additional AE added" no update has been there in the corresponding AE eCRF, Please review and update accordingly, else clarify.' (Site from DM).  |                        | 19 Feb 2021 11:54:03 |
| User closed query 'Per DM CLR: Narrative indicates that the subject had a FALL that resulted to this AE. However, there is no corresponding AE record of Fall that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.b' (Site from DM).                          |                        | 19 Feb 2021 11:54:03 |
| Query 'Per DM CLR: Narrative indicates that the subject had a FALL that resulted to this AE. However, there is no corresponding AE record of Fall that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.b' answered with 'Additional AE added ' (Site from DM). |                        | 18 Feb 2021 19:57:20 |
| User opened query 'Per DM CLR: Narrative indicates that the subject had a FALL that resulted to this AE. However, there is no corresponding AE record of Fall that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.b' (Site from DM).                          |                        | 16 Feb 2021 11:19:01 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Narrative](#)

| Audit   | User                       | Time (GMT)                   |
|---|----------------------------|------------------------------|
| User closed query 'Per DM CLR: SAE Narrative = SHE HAD BEEN HOSPITALIZED FOR THREE DAYS DUE TO A SUBDURAL HEMATOMA SUFFERED AFTER A FALL. However, please review and verify if FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).  | (b) (4), (b) (6)           | 22 Jan 2021 21:20:38         |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).  |                            | 20 Jan 2021 21:23:23         |
| User closed query 'PV Query: Please clarify whether the subject was conscious during the fall. Please provide information regarding vitals during the fall, if applicable. ' (Site from Safety).  |                            | 20 Jan 2021 21:23:19         |
| User closed query 'PV Query: Please provide the results (including dates) for CT scans performed during intake and discharge. Please provide any other relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).   |                            | 20 Jan 2021 21:23:12         |
| Query 'Per DM CLR: SAE Narrative = SHE HAD BEEN HOSPITALIZED FOR THREE DAYS DUE TO A SUBDURAL HEMATOMA SUFFERED AFTER A FALL. However, please review and verify if FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'subject refused to release medical records' (Site from DM).   | Victoria Hernandez (b) (4) | (b) (4) 19 Jan 2021 16:50:06 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' answered with 'subject refused to release medical records' (Site from Safety). | Victoria Hernandez (b) (4) | (b) (4) 19 Jan 2021 16:49:51 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Narrative](#)

| Audit  | User                       | Time (GMT)                   |
|--|----------------------------|------------------------------|
| Query 'PV Query: Please clarify whether the subject was conscious during the fall. Please provide information regarding vitals during the fall, if applicable. ' answered with 'subject refused to release medical records' (Site from Safety).  | Victoria Hernandez (b) (4) | (b) (4) 19 Jan 2021 16:49:42 |
| Query 'PV Query: Please provide the results (including dates) for CT scans performed during intake and discharge. Please provide any other relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'subject refused to release medical records' (Site from Safety).                                 | Victoria Hernandez (b) (4) | (b) (4) 19 Jan 2021 16:49:36 |
| DataPoint Un-verified.   | (b) (4), (b) (6)           | 18 Jan 2021 19:49:57         |
| DataPoint Verified.  |                            | 18 Jan 2021 19:47:43         |
| User opened query 'Per DM CLR: SAE Narrative = SHE HAD BEEN HOSPITALIZED FOR THREE DAYS DUE TO A SUBDURAL HEMATOMA SUFFERED AFTER A FALL. However, please review and verify if FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).   |                            | 08 Dec 2020 05:58:27         |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety). |                            | 30 Nov 2020 23:05:53         |
| User opened query 'PV Query: Please clarify whether the subject was conscious during the fall. Please provide information regarding vitals during the fall, if applicable. ' (Site from Safety).   |                            | 30 Nov 2020 23:05:41         |
| User opened query 'PV Query: Please provide the results (including dates) for CT scans performed during intake and discharge. Please provide any other relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).  |                            | 30 Nov 2020 23:05:27         |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:20:34

[Narrative](#)

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| User entered 'Patient called staff on 20NOV2020 to report that she had been hospitalized for three days due to a subdural hematoma suffered after a fall. Patient does have a medical history of rod implant due to scoliosis and a total hip replacement due to Rheumatoid arthritis, which she claims, contributed to her fall. Patient states she was tested for COVID-19 and tests came back negative. Intake and discharge CT scans completed and Keppra was prescribed while inpatient to prevent seizures. Medical records will be requested asap.' | Antonio Gutierrez (b) (4) | 20 Nov 2020 21:51:16 |

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 20 Nov 2020 21:51:16 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 10:36:28 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

[Adverse event](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 29 Apr 2021 10:36:28 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 16 Apr 2021 16:59:37 |
| User signature succeeded.   | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\23.0. | Coder Import (b) (4)   | 23 Mar 2021 18:40:59 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)   | 23 Mar 2021 18:40:59 |
| Data point term sent to Coder   | System                 | 23 Mar 2021 18:39:19 |
| User entered 'Fall'   | Dawn Killian (b) (4)   | 23 Mar 2021 18:39:18 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Was this a medically-attended AE?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'Yes (Y)'    | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'No (N)'     | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'No (N)'     | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '14 Nov 2020' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 10:36:28 |
| User entered empty. | System           | 23 Mar 2021 18:39:18 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'No (N)'     | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '14 Nov 2020' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

**End time (00:00-23:59)**

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 10:36:28 |
| User entered empty. | System           | 23 Mar 2021 18:39:18 |



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Severity](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                              | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.                            | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded.                      | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

US3292103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

[Is the adverse event serious?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'No (N)'     | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

US3292103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

[Death](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '0'          | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

[Life threatening](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '0'          | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '0'          | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

US3292103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

Hospital Discharge Date (dd MMM yyyy)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Admitted to ICU?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

[Number of Days in ICU](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

[Persistent or significant disability or incapacity](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '0'          | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Congenital anomaly or birth defect](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '0'          | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Other medically important event](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '0'          | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Relationship to investigational product](#)

| Audit                                    | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.                      | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded.                | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

[Relationship to Study Procedure](#)

| Audit                                    | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.                      | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded.                | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

[Action taken with investigational product](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'None (NONE)' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

US3292103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

None

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 29 Apr 2021 10:36:28 |
| DataPoint Verified.  | (b) (4), (b) (6)                | 16 Apr 2021 16:59:37 |
| User signature succeeded.  | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| User closed query 'Other action taken is missing.<br>Please check at least one action from the options<br>provided.' (Site from System). | (b) (4)<br>System               | 15 Apr 2021 20:07:17 |
| User entered '1' reason for change: Data Entry Error   | (b) (4), (b) (6)                | 15 Apr 2021 20:07:17 |
| User opened query 'Other action taken is missing.<br>Please check at least one action from the options<br>provided.' (Site from System). | System                          | 15 Apr 2021 19:27:39 |
| User entered '0'   | Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

[Concomitant Medication](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 29 Apr 2021 10:36:28 |
| User closed query 'Per CDM: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or mention the CM logline number related to this Thank you .' (Site from DM).<br>DataPoint Verified.   | (b) (4), (b) (6)       | 21 Apr 2021 16:04:09 |
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| Query 'Per CDM: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or mention the CM logline number related to this Thank you .' answered with '"None" is selected per source.' (Site from DM).<br>User entered '0' reason for change: Data Entry Error | (b) (4), (b) (6)       | 15 Apr 2021 21:03:50 |
| User opened query 'Per CDM: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or mention the CM logline number related to this Thank you .' (Site from DM).  | (b) (4), (b) (6)       | 15 Apr 2021 19:27:39 |
| User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).  | (b) (4), (b) (6)       | 15 Apr 2021 12:56:52 |

US3292103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

[Concomitant Medication](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.<br />' answered with 'updated' (Site from DM). | Kristy Trevino (b) (4) | 12 Apr 2021 18:21:50 |
| User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken.                                    | (b) (4), (b) (6)       | 03 Apr 2021 10:54:56 |
| ' (Site from DM).<br>User entered 'I'   | Dawn Killian (b) (4)   | 23 Mar 2021 18:39:18 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

[Concomitant Procedure](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '0'          | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:20:34

[Outcome](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.                                       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded.                                 | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'Recovered/Resolved<br>(RECOVERED/RESOLVED)' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Narrative](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 29 Apr 2021 10:36:28 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 16 Apr 2021 16:59:37 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:39:18 |

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 10:36:28 |
| User entered '0'  | System           | 23 Mar 2021 18:39:18 |

**US3292103**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 10:36:28 |
| User entered 'I'  | System           | 23 Mar 2021 18:39:18 |



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 10:36:28 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:20:34

Were any prior/concomitant medications and/or vaccinations taken?

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 03 May 2021 05:13:16 |
| User closed query 'Please add ConMeds Flu Shot, Pneumovax and tetanus vaccines to con med CRF.' (Site from CRA).              | (b) (4), (b) (6)                  | 20 Apr 2021 20:44:54 |
| Query 'Please add ConMeds Flu Shot, Pneumovax and tetanus vaccines to con med CRF.' answered with 'updated ' (Site from CRA). | Dawn Killian (b) (4)<br>(b) (4)   | 23 Mar 2021 18:40:19 |
| User opened query 'Please add ConMeds Flu Shot, Pneumovax and tetanus vaccines to con med CRF.' (Site from CRA).              | (b) (4), (b) (6)                  | 10 Mar 2021 18:06:11 |
| DataPoint Verified.   | (b) (4), (b) (6)                  | 10 Mar 2021 17:13:50 |
| User signature succeeded.   | Douglas Denham (b) (4)<br>(b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'  | (b) (4), (b) (6)                  | 11 Aug 2020 16:09:16 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit  | User  | Time (GMT)                                   |
|--|---|--|
| User signature succeeded.  | Douglas Denham (b) (4)                          | 16 Apr 2021 14:02:04                         |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)                     | 10 Mar 2021 17:15:41                         |
| 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)                 | 17 Sep 2020 16:55:39                         |
| 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)                 | 17 Sep 2020 16:55:39                         |
| Data point term sent to Coder Coding entries removed.  | System<br>Victoria Hernandez (b) (4)<br>(b) (4) | 17 Sep 2020 16:55:05<br>17 Sep 2020 16:54:10 |
| 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)                 | 11 Aug 2020 16:12:21                         |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)                 | 11 Aug 2020 16:12:21                         |
| Data point term sent to Coder User entered 'Tylenol'   | System<br>(b) (4), (b) (6)                      | 11 Aug 2020 16:10:48<br>11 Aug 2020 16:10:08 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:15:41 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 11 Aug 2020 16:10:08 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit  | User                                  | Time (GMT)           |
|--|---------------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)                | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)           | 10 Mar 2021 17:15:41 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).             | (b) (4), (b) (6)                      | 29 Sep 2020 13:50:19 |
| Query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4)<br>(b) (4) | 17 Sep 2020 16:54:26 |
| User entered 'GENERALIZED JOINT PAIN' reason for change: Data Entry Error  | Victoria Hernandez (b) (4)<br>(b) (4) | 17 Sep 2020 16:54:10 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location of JOINT PAIN (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).             | (b) (4), (b) (6)                      | 17 Sep 2020 11:51:39 |
| User entered 'joint pain'  | (b) (4), (b) (6)                      | 11 Aug 2020 16:10:08 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:15:41 |
| User entered '325'        | (b) (4), (b) (6)            | 11 Aug 2020 16:10:08 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:15:41 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:10:08 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:15:41 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:10:08 |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:15:41 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6)            | 11 Aug 2020 16:10:08 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:20:34

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:15:41 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:10:08 |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:15:41 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:10:08 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:20:34**

If route of administration is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:15:41 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:10:08 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:15:41 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:10:13 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:10:14 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:10:08 |
| User entered 'un UNK 2000'   | (b) (4), (b) (6)       | 11 Aug 2020 16:10:08 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:20:34

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:15:41 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:10:08 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:15:41 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:10:08 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:15:41 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:10:08 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:15:41 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:10:08 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 16:10:08 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 16:10:08 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 16:10:08 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                | 23 Apr 2021 14:10:32 |
| User signature succeeded.  | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM CITRATE - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 14 Aug 2020 06:52:18 |
| 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) | 14 Aug 2020 06:52:18 |
| Data point term sent to Coder  | System                          | 11 Aug 2020 16:11:50 |
| User entered 'Magnesium citrate'   | (b) (4), (b) (6)                | 11 Aug 2020 16:11:05 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:20:34

[Prophylaxis](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:17:47 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Victoria Hernandez (b) (4)  | 19 Jan 2021 16:39:03 |
| User entered 'No (N)'                                      | (b) (4)<br>(b) (4), (b) (6) | 11 Aug 2020 16:11:05 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit   | User                                  | Time (GMT)           |
|---|---------------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)                | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)           | 10 Mar 2021 17:17:44 |
| User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).             | (b) (4), (b) (6)                      | 19 Jan 2021 20:48:14 |
| Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM). | Victoria Hernandez (b) (4)<br>(b) (4) | 19 Jan 2021 16:39:09 |
| User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).             | (b) (4), (b) (6)                      | 19 Jan 2021 13:42:13 |
| User entered 'General health'   | (b) (4), (b) (6)                      | 11 Aug 2020 16:11:05 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| User closed query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified.  | (b) (4), (b) (6)           | 23 Apr 2021 21:41:32 |
|   | (b) (4), (b) (6)           | 23 Apr 2021 21:41:31 |
| Query 'Con med source yet to be updated. Please reconcile. ' answered with 'updated in source' (Site from CRA).   | (b) (4), (b) (6)           | 23 Apr 2021 21:33:01 |
| User opened query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).   | (b) (4), (b) (6)           | 23 Apr 2021 14:11:14 |
| User closed query 'Please provide updated dose in source.' (Site from CRA).   | (b) (4), (b) (6)           | 23 Apr 2021 14:11:14 |
| User signature succeeded.   | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
|   | (b) (4)                    |                      |
| Query 'Please provide updated dose in source.' answered with 'updated' (Site from CRA).   | Victoria Hernandez (b) (4) | 12 Mar 2021 18:46:05 |
|   | (b) (4)                    |                      |
| User opened query 'Please provide updated dose in source.' (Site from CRA).   | (b) (4), (b) (6)           | 10 Mar 2021 17:17:42 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. | (b) (4), (b) (6)           | 29 Sep 2020 13:52:10 |
| ' (Site from DM).   |                            |                      |
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.             | Victoria Hernandez (b) (4) | 17 Sep 2020 16:58:27 |
| ' answered with 'UPDATED PER SUBJECT' (Site from DM).   | (b) (4)                    |                      |
| User entered '250' reason for change: New Information   | Victoria Hernandez (b) (4) | 17 Sep 2020 16:57:50 |
|   | (b) (4)                    |                      |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. | (b) (4), (b) (6)           | 17 Sep 2020 11:51:17 |
| ' (Site from DM).   |                            |                      |
| User entered 'I'  | (b) (4), (b) (6)           | 11 Aug 2020 16:11:05 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| User closed query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified. | (b) (4), (b) (6)           | 23 Apr 2021 21:41:37 |
|  | (b) (4), (b) (6)           | 23 Apr 2021 21:41:34 |
| Query 'Con med source yet to be updated. Please reconcile. ' answered with 'updated in source' (Site from CRA).  | (b) (4), (b) (6)           | 23 Apr 2021 21:33:03 |
| User opened query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).                        | (b) (4), (b) (6)           | 23 Apr 2021 14:11:32 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
|  | (b) (4)                    |                      |
| User entered 'mg (mg)' reason for change: New Information  | Victoria Hernandez (b) (4) | 17 Sep 2020 16:57:50 |
|  | (b) (4)                    |                      |
| User entered 'tablet (TABLET)'   | (b) (4), (b) (6)           | 11 Aug 2020 16:11:05 |
|  |                            |                      |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:20:34**

[If dose unit is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Apr 2021 14:11:35 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:11:05 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Frequency](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)       | 23 Apr 2021 14:11:37 |
| User signature succeeded.      | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)       | 11 Aug 2020 16:11:05 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:20:34**

[If frequency is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Apr 2021 14:11:39 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:11:05 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Route of administration](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 23 Apr 2021 14:11:40 |
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)       | 11 Aug 2020 16:11:05 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:20:34**

[If route of administration is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Apr 2021 14:11:42 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:11:05 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)       | 23 Apr 2021 14:11:49 |
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:10:22 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:11:08 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:11:05 |
| User entered 'un UNK 2014'   | (b) (4), (b) (6)       | 11 Aug 2020 16:11:05 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Apr 2021 14:11:55 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:11:05 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Apr 2021 14:11:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:11:05 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:20:34**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Apr 2021 14:11:58 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:11:05 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Apr 2021 14:11:59 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:11:05 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:11:05 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:11:05 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:11:05 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit   | User                                 | Time (GMT)                                   |
|---|--------------------------------------|--|
| User signature succeeded.   | Douglas Denham (b) (4)               | 16 Apr 2021 14:02:04                         |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)          | 10 Mar 2021 17:25:27                         |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 26 Oct 2020 19:04:07                         |
| 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)      | 26 Oct 2020 19:04:07                         |
| Data point term sent to Coder Coding entries removed.   | System<br>Victoria Hernandez (b) (4) | 26 Oct 2020 17:57:34<br>26 Oct 2020 17:57:31 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 11 Aug 2020 16:13:20                         |
| 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)      | 11 Aug 2020 16:13:20                         |
| Data point term sent to Coder User entered 'allegra'  | System<br>(b) (4), (b) (6)           | 11 Aug 2020 16:11:52<br>11 Aug 2020 16:11:38 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:20:34**

[Prophylaxis](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:25:28 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:11:38 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit   | User                                  | Time (GMT)           |
|---|---------------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)                | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)           | 10 Mar 2021 17:25:34 |
| User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match.' (Site from DM).             | (b) (4), (b) (6)                      | 30 Nov 2020 10:25:28 |
| Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match.' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4)<br>(b) (4) | 26 Oct 2020 17:57:47 |
| User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error   | Victoria Hernandez (b) (4)<br>(b) (4) | 26 Oct 2020 17:57:31 |
| User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with MH entries so there is an appropriate match.' (Site from DM).             | (b) (4), (b) (6)                      | 22 Oct 2020 02:39:03 |
| User entered 'allergies'  | (b) (4), (b) (6)                      | 11 Aug 2020 16:11:38 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| User closed query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified.   | (b) (4), (b) (6)           | 23 Apr 2021 21:41:46 |
|  | (b) (4), (b) (6)           | 23 Apr 2021 21:41:45 |
| Query 'Con med source yet to be updated. Please reconcile. ' answered with 'updated' (Site from CRA).  | (b) (4), (b) (6)           | 23 Apr 2021 21:33:39 |
| User opened query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).  | (b) (4), (b) (6)           | 23 Apr 2021 14:12:40 |
| User closed query 'Please update dose in source.' (Site from CRA).   | (b) (4), (b) (6)           | 23 Apr 2021 14:12:40 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
|  | (b) (4)                    |                      |
| Query 'Please update dose in source.' answered with 'updated' (Site from CRA).   | Victoria Hernandez (b) (4) | 12 Mar 2021 18:45:49 |
|  | (b) (4)                    |                      |
| User opened query 'Please update dose in source.' (Site from CRA).   | (b) (4), (b) (6)           | 10 Mar 2021 17:25:20 |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.<br>' (Site from DM).                         | (b) (4), (b) (6)           | 29 Sep 2020 13:53:15 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.<br>' answered with 'UPDATED PER SUBJECT' (Site from DM). | Victoria Hernandez (b) (4) | 17 Sep 2020 17:02:36 |
|  | (b) (4)                    |                      |
| User entered '180' reason for change: New Information  | Victoria Hernandez (b) (4) | 17 Sep 2020 17:00:13 |
|  | (b) (4)                    |                      |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.<br>' (Site from DM).                         | (b) (4), (b) (6)           | 17 Sep 2020 10:37:13 |
| User entered '20'  | (b) (4), (b) (6)           | 11 Aug 2020 16:11:38 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:25:37 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:11:38 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:25:39 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:11:38 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:25:41 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6)            | 11 Aug 2020 16:11:38 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:20:34

If frequency is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:25:43 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:11:38 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:20:34**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:25:47 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:11:38 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:20:34**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:25:49 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:11:38 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:25:51 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:10:29 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:12:18 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:11:38 |
| User entered 'un UNK 2019'   | (b) (4), (b) (6)       | 11 Aug 2020 16:11:38 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:20:34

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:25:53 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:11:38 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:25:58 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:11:38 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:26:00 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:11:38 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:26:05 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:11:38 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 16:11:38 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 16:11:38 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 16:11:38 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 10 Mar 2021 17:27:05 |
| User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 16:14:16 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 16:14:16 |
| Data point term sent to Coder   | System                          | 11 Aug 2020 16:12:57 |
| User entered 'fish oil'   | (b) (4), (b) (6)                | 11 Aug 2020 16:12:11 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:20:34

[Prophylaxis](#)

| Audit   | User                                  | Time (GMT)           |
|---|---------------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)                | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)           | 10 Mar 2021 17:27:07 |
| User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).             | (b) (4), (b) (6)                      | 19 Jan 2021 20:49:05 |
| Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM). | Victoria Hernandez (b) (4)<br>(b) (4) | 19 Jan 2021 16:39:31 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Victoria Hernandez (b) (4)<br>(b) (4) | 19 Jan 2021 16:39:21 |
| User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).             | (b) (4), (b) (6)                      | 19 Jan 2021 13:42:30 |
| User entered 'No (N)'   | (b) (4), (b) (6)                      | 11 Aug 2020 16:12:11 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit                         | User                   | Time (GMT)           |
|-------------------------------|------------------------|----------------------|
| User signature succeeded.     | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.           | (b) (4)                |                      |
|                               | (b) (4), (b) (6)       | 10 Mar 2021 17:27:13 |
| User entered 'general health' | (b) (4), (b) (6)       | 11 Aug 2020 16:12:11 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| User closed query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified.   | (b) (4), (b) (6)           | 23 Apr 2021 21:41:54 |
|  | (b) (4), (b) (6)           | 23 Apr 2021 21:41:53 |
| Query 'Con med source yet to be updated. Please reconcile. ' answered with 'updated' (Site from CRA).  | (b) (4), (b) (6)           | 23 Apr 2021 21:34:35 |
| User opened query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).  | (b) (4), (b) (6)           | 23 Apr 2021 14:13:22 |
| User closed query 'Please provide updated dose in source.' (Site from CRA).  | (b) (4), (b) (6)           | 23 Apr 2021 14:13:22 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
|  | (b) (4)                    |                      |
| Query 'Please provide updated dose in source.' answered with 'updated' (Site from CRA).  | Victoria Hernandez (b) (4) | 12 Mar 2021 18:46:23 |
|  | (b) (4)                    |                      |
| User opened query 'Please provide updated dose in source.' (Site from CRA).  | (b) (4), (b) (6)           | 10 Mar 2021 17:26:58 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication 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 Sep 2020 13:54:12 |
| Query 'Per DM CLR: Please provide the actual dose for this medication 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 'UPDATED PER SUBJECT' (Site from DM). | Victoria Hernandez (b) (4) | 17 Sep 2020 17:04:29 |
|  | (b) (4)                    |                      |
| User entered '1000' reason for change: New Information   | Victoria Hernandez (b) (4) | 17 Sep 2020 17:04:07 |
|  | (b) (4)                    |                      |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication 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)           | 17 Sep 2020 11:50:56 |
| User entered 'I'   | (b) (4), (b) (6)           | 11 Aug 2020 16:12:11 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| User closed query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified. | (b) (4), (b) (6)           | 23 Apr 2021 21:41:58 |
|  |                            | 23 Apr 2021 21:41:56 |
| Query 'Con med source yet to be updated. Please reconcile. ' answered with 'updated' (Site from CRA).            |                            | 23 Apr 2021 21:34:40 |
| User opened query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).                        |                            | 23 Apr 2021 14:13:11 |
| User closed query 'Please provide updated dose in source.' (Site from CRA).                                      |                            | 23 Apr 2021 14:13:11 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
|  | (b) (4)                    |                      |
| Query 'Please provide updated dose in source.' answered with 'updated' (Site from CRA).                          | Victoria Hernandez (b) (4) | 12 Mar 2021 18:46:52 |
|  | (b) (4)                    |                      |
| User opened query 'Please provide updated dose in source.' (Site from CRA).                                      | (b) (4), (b) (6)           | 10 Mar 2021 17:27:03 |
|  |                            |                      |
| User entered 'mg (mg)' reason for change: New Information  | Victoria Hernandez (b) (4) | 17 Sep 2020 17:04:07 |
|  | (b) (4)                    |                      |
| User entered 'tablet (TABLET)'   | (b) (4), (b) (6)           | 11 Aug 2020 16:12:11 |
|  |                            |                      |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:27:17 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:12:11 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:27:25 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 11 Aug 2020 16:12:11 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:20:34

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:27:27 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:12:11 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:20:34

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:27:35 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:12:11 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:20:34**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:27:38 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:12:11 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:27:44 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:10:39 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:12:13 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:12:11 |
| User entered 'un UNK 2015'   | (b) (4), (b) (6)       | 11 Aug 2020 16:12:11 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:20:34

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:27:47 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:12:11 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:27:50 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:12:11 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:27:52 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:12:11 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:27:56 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 11 Aug 2020 16:12:11 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:12:11 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:12:11 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:12:11 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 10 Mar 2021 17:28:35 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 02 Oct 2020 19:00:01 |
| 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) | 02 Oct 2020 19:00:01 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:20:34

Name of Medication

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE, PRODUCTSYNONYM: CENTRUM SILVER [ASCORBIC ACID;BIOTIN;CALCIUM;CALCIUM PHOSPHATE DIBASIC;CHROMIC CHLORIDE;CUPRIC OXIDE;CYANOCOBALAMIN;FERROUS FUMARATE;FOLIC ACID;MAGNESIUM OXIDE;MANGANESE SULFATE;NICKEL SULFATE;NICOTINAMIDE;PANTOTHENIC ACID;PHYTOMENADIONE;POTASSIUM CHLORIDE;POTASSIUM IODIDE;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SODIUM METASILICATE;SODIUM MOLYBDATE;SODIUM SELENATE;THIAMINE MONONITRATE;TOCOPHERYL ACETATE;VITAMIN D NOS;ZINC OXIDE] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 15 Sep 2020 17:31:53 |
| 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) | 15 Sep 2020 17:31:53 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Aug 2020 16:15:22 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4) | 11 Aug 2020 16:15:22 |
| Data point term sent to Coder   | System               | 11 Aug 2020 16:14:01 |
| User entered 'centrum silver'   | (b) (4), (b) (6)     | 11 Aug 2020 16:13:18 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:20:34

[Prophylaxis](#)

| Audit   | User                                  | Time (GMT)           |
|---|---------------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)                | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)           | 10 Mar 2021 17:28:35 |
| User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).             | (b) (4), (b) (6)                      | 19 Jan 2021 20:49:45 |
| Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM). | Victoria Hernandez (b) (4)<br>(b) (4) | 19 Jan 2021 16:39:53 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Victoria Hernandez (b) (4)<br>(b) (4) | 19 Jan 2021 16:39:48 |
| User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).             | (b) (4), (b) (6)                      | 19 Jan 2021 13:42:39 |
| User entered 'No (N)'   | (b) (4), (b) (6)                      | 11 Aug 2020 16:13:18 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| User signature succeeded.     | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.           | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:28:35 |
| User entered 'general health' | (b) (4), (b) (6)            | 11 Aug 2020 16:13:18 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:20:34**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:28:35 |
| User entered 'l'          | (b) (4), (b) (6)            | 11 Aug 2020 16:13:18 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:28:35 |
| User entered 'tablet (TABLET)' | (b) (4), (b) (6)            | 11 Aug 2020 16:13:18 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:28:35 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:13:18 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)                |                      |
|                                | (b) (4), (b) (6)       | 10 Mar 2021 17:28:35 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)       | 11 Aug 2020 16:13:18 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:20:34

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:28:35 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:13:18 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:20:34

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:28:35 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:13:18 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:20:34**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:28:35 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:13:18 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:28:35 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:10:45 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:13:21 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:13:18 |
| User entered 'un UNK 2015'   | (b) (4), (b) (6)       | 11 Aug 2020 16:13:18 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:28:35 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:13:18 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:28:35 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:13:18 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:28:35 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:13:18 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:28:35 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 11 Aug 2020 16:13:18 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:13:18 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:13:18 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:13:18 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 10 Mar 2021 17:29:23 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: VITAMIN K AND OTHER HEMOSTATICS, ATC: VITAMIN K, PRODUCT: VITAMIN K NOS, PRODUCTSYNONYM: VITAMIN K [VITAMIN K NOS] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 16:15:21 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 16:15:21 |
| Data point term sent to Coder   | System                          | 11 Aug 2020 16:14:02 |
| User entered 'Vitamin K'  | (b) (4), (b) (6)                | 11 Aug 2020 16:14:01 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:20:34

[Prophylaxis](#)

| Audit  | User                                  | Time (GMT)           |
|--|---------------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)                | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)           | 10 Mar 2021 17:29:26 |
| User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.<br>' (Site from DM).             | (b) (4), (b) (6)                      | 19 Jan 2021 13:42:47 |
| Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.<br>' answered with 'updated' (Site from DM). | Victoria Hernandez (b) (4)<br>(b) (4) | 18 Jan 2021 19:56:18 |
| User entered 'Yes (Y)' reason for change: Data Entry Error   | Victoria Hernandez (b) (4)<br>(b) (4) | 18 Jan 2021 19:56:11 |
| User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.<br>' (Site from DM).             | (b) (4), (b) (6)                      | 16 Jan 2021 18:40:22 |
| User entered 'No (N)'  | (b) (4), (b) (6)                      | 11 Aug 2020 16:14:01 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit                         | User                   | Time (GMT)           |
|-------------------------------|------------------------|----------------------|
| User signature succeeded.     | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.           | (b) (4)                |                      |
|                               | (b) (4), (b) (6)       | 10 Mar 2021 17:29:29 |
| User entered 'General health' | (b) (4), (b) (6)       | 11 Aug 2020 16:14:01 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| User closed query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified.  | (b) (4), (b) (6)           | 23 Apr 2021 21:42:13 |
|   |                            | 23 Apr 2021 21:42:12 |
| Query 'Con med source yet to be updated. Please reconcile. ' answered with 'updated' (Site from CRA).   |                            | 23 Apr 2021 21:35:27 |
| User opened query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).   |                            | 23 Apr 2021 14:13:52 |
| User closed query 'Please provide updated dose in con med source' (Site from CRA).  |                            | 23 Apr 2021 14:13:52 |
| User signature succeeded.   | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
|   | (b) (4)                    |                      |
| Query 'Please provide updated dose in con med source' answered with 'updated' (Site from CRA).  | Victoria Hernandez (b) (4) | 12 Mar 2021 18:47:46 |
| User opened query 'Please provide updated dose in con med source' (Site from CRA).  | (b) (4)                    |                      |
|   | (b) (4), (b) (6)           | 10 Mar 2021 17:29:11 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. | (b) (4), (b) (6)           | 29 Sep 2020 13:55:08 |
| ' (Site from DM).   |                            |                      |
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.             | Victoria Hernandez (b) (4) | 17 Sep 2020 17:13:37 |
| ' answered with 'UPDATED PERSUBJECT' (Site from DM).  | (b) (4)                    |                      |
| User entered '100' reason for change: New Information   | Victoria Hernandez (b) (4) | 17 Sep 2020 17:13:13 |
|   | (b) (4)                    |                      |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. | (b) (4), (b) (6)           | 17 Sep 2020 11:52:40 |
| ' (Site from DM).   |                            |                      |
| User entered 'I'  | (b) (4), (b) (6)           | 11 Aug 2020 16:14:01 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| User closed query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified.   | (b) (4), (b) (6)           | 23 Apr 2021 21:42:21 |
|  |                            | 23 Apr 2021 21:42:20 |
| Query 'Con med source yet to be updated. Please reconcile. ' answered with 'updated' (Site from CRA).  |                            | 23 Apr 2021 21:35:32 |
| User opened query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).  |                            | 23 Apr 2021 14:13:58 |
| User closed query 'Please provide updated dose in con med source' (Site from CRA).   |                            | 23 Apr 2021 14:13:58 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
|  | (b) (4)                    |                      |
| Query 'Please provide updated dose in con med source' answered with 'updated' (Site from CRA).   | Victoria Hernandez (b) (4) | 12 Mar 2021 18:47:54 |
| User opened query 'Please provide updated dose in con med source' (Site from CRA).   | (b) (4)                    |                      |
|  | (b) (4), (b) (6)           | 10 Mar 2021 17:29:18 |
| User closed query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).             | (b) (4), (b) (6)           | 25 Nov 2020 17:33:38 |
| Query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'UPDATED' (Site from DM). | Victoria Hernandez (b) (4) | 26 Oct 2020 18:01:08 |
|  | (b) (4)                    |                      |
| User entered 'ug (ug)' reason for change: Data Entry Error   | Victoria Hernandez (b) (4) | 26 Oct 2020 18:00:58 |
|  | (b) (4)                    |                      |
| User opened query 'Per DM CLR: Please review "Other Unit" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).             | (b) (4), (b) (6)           | 22 Oct 2020 05:59:07 |
|  |                            |                      |
| User entered 'Other (OTHER)' reason for change: Data Entry Error   | Victoria Hernandez (b) (4) | 17 Sep 2020 17:13:13 |
|  | (b) (4)                    |                      |
| User entered 'tablet (TABLET)'   | (b) (4), (b) (6)           | 11 Aug 2020 16:14:01 |
|  |                            |                      |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| User signature succeeded.                             | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
| DataPoint Verified.                                   | (b) (4)                    |                      |
|   | (b) (4), (b) (6)           | 10 Mar 2021 17:30:02 |
| User entered empty; reason for change New Information | Victoria Hernandez (b) (4) | 26 Oct 2020 18:00:58 |
| User entered 'mcg' reason for change: New Information | (b) (4)                    |                      |
|   | Victoria Hernandez (b) (4) | 17 Sep 2020 17:13:13 |
| User entered empty.                                   | (b) (4)                    |                      |
|   | (b) (4), (b) (6)           | 11 Aug 2020 16:14:01 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:30:06 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 11 Aug 2020 16:14:01 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:20:34**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:30:09 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:14:01 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:20:34

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:30:12 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:14:01 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:20:34

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:30:18 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:14:01 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:30:37 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:10:51 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:14:04 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:14:01 |
| User entered 'un UNK 2015'   | (b) (4), (b) (6)       | 11 Aug 2020 16:14:01 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:20:34

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:30:58 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:14:01 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:31:05 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:14:01 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:31:07 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:14:01 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:31:08 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:14:01 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:14:01 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:14:01 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:14:01 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 10 Mar 2021 17:32:04 |
| 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: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 16:16:12 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.   | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 16:16:12 |
| Data point term sent to Coder  | System                          | 11 Aug 2020 16:15:04 |
| User entered 'vitamin D3'  | (b) (4), (b) (6)                | 11 Aug 2020 16:14:41 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:20:34

[Prophylaxis](#)

| Audit   | User                                  | Time (GMT)           |
|---|---------------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)                | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)           | 10 Mar 2021 17:32:24 |
| User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).             | (b) (4), (b) (6)                      | 19 Jan 2021 20:50:28 |
| Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM). | Victoria Hernandez (b) (4)<br>(b) (4) | 19 Jan 2021 16:40:06 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Victoria Hernandez (b) (4)<br>(b) (4) | 19 Jan 2021 16:40:01 |
| User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).             | (b) (4), (b) (6)                      | 19 Jan 2021 13:42:59 |
| User entered 'No (N)'   | (b) (4), (b) (6)                      | 11 Aug 2020 16:14:41 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| User signature succeeded.     | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.           | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:32:29 |
| User entered 'GENERAL HEALTH' | (b) (4), (b) (6)            | 11 Aug 2020 16:14:41 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| User closed query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified.  | (b) (4), (b) (6)           | 23 Apr 2021 21:42:32 |
|   |                            | 23 Apr 2021 21:42:31 |
| Query 'Con med source yet to be updated. Please reconcile. ' answered with 'updated' (Site from CRA).   |                            | 23 Apr 2021 21:36:06 |
| User opened query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).   |                            | 23 Apr 2021 14:14:17 |
| User closed query 'Please provide updated dose in con med source' (Site from CRA).  |                            | 23 Apr 2021 14:14:17 |
| User signature succeeded.   | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
|   | (b) (4)                    |                      |
| Query 'Please provide updated dose in con med source' answered with 'updated' (Site from CRA).  | Victoria Hernandez (b) (4) | 12 Mar 2021 19:18:19 |
| User opened query 'Please provide updated dose in con med source' (Site from CRA).  | (b) (4)                    |                      |
|   | (b) (4), (b) (6)           | 10 Mar 2021 17:34:30 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. | (b) (4), (b) (6)           | 29 Sep 2020 13:55:43 |
| ' (Site from DM).   |                            |                      |
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.             | Victoria Hernandez (b) (4) | 17 Sep 2020 17:16:52 |
| ' answered with 'UPDATED PER SUBJECT' (Site from DM).   | (b) (4)                    |                      |
| User entered '1000' reason for change: New Information  | Victoria Hernandez (b) (4) | 17 Sep 2020 17:16:11 |
|   | (b) (4)                    |                      |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. | (b) (4), (b) (6)           | 17 Sep 2020 11:52:19 |
| ' (Site from DM).   |                            |                      |
| User entered 'I'  | (b) (4), (b) (6)           | 11 Aug 2020 16:14:41 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| User closed query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified. | (b) (4), (b) (6)           | 23 Apr 2021 21:42:36 |
|  |                            | 23 Apr 2021 21:42:34 |
| Query 'Con med source yet to be updated. Please reconcile. ' answered with 'updated' (Site from CRA).            |                            | 23 Apr 2021 21:36:10 |
| User opened query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).                        |                            | 23 Apr 2021 14:14:22 |
| User closed query 'Please provide updated dose in con med source' (Site from CRA).                               |                            | 23 Apr 2021 14:14:22 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
|  | (b) (4)                    |                      |
| Query 'Please provide updated dose in con med source' answered with 'updated' (Site from CRA).                   | Victoria Hernandez (b) (4) | 12 Mar 2021 19:18:26 |
|  | (b) (4)                    |                      |
| User opened query 'Please provide updated dose in con med source' (Site from CRA).                               | (b) (4), (b) (6)           | 10 Mar 2021 17:34:43 |
|  |                            |                      |
| User entered 'IU (IU)' reason for change: New Information  | Victoria Hernandez (b) (4) | 17 Sep 2020 17:16:11 |
|  | (b) (4)                    |                      |
| User entered 'tablet (TABLET)'   | (b) (4), (b) (6)           | 11 Aug 2020 16:14:41 |
|  |                            |                      |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:34:46 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:14:41 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:20:34**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:34:55 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 11 Aug 2020 16:14:41 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:20:34

[If frequency is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:34:58 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:14:41 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:20:34**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:35:16 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:14:41 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:20:34**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:35:20 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:14:41 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:35:28 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:10:57 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:14:44 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:14:41 |
| User entered 'UN UNK 2015'   | (b) (4), (b) (6)       | 11 Aug 2020 16:14:41 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:20:34

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:35:33 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:14:41 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:36:33 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:14:41 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:36:35 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:14:41 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:36:39 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:14:41 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:14:41 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:14:41 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:14:41 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 10 Mar 2021 17:37:02 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 16:17:09 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.  | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 16:17:09 |
| Data point term sent to Coder   | System                          | 11 Aug 2020 16:16:05 |
| User entered 'CALCIUM'  | (b) (4), (b) (6)                | 11 Aug 2020 16:15:08 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:20:34

[Prophylaxis](#)

| Audit   | User                                  | Time (GMT)           |
|---|---------------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)                | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)           | 10 Mar 2021 17:37:07 |
| User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).             | (b) (4), (b) (6)                      | 19 Jan 2021 20:51:10 |
| Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM). | Victoria Hernandez (b) (4)<br>(b) (4) | 19 Jan 2021 16:40:18 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Victoria Hernandez (b) (4)<br>(b) (4) | 19 Jan 2021 16:40:13 |
| User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).             | (b) (4), (b) (6)                      | 19 Jan 2021 13:43:07 |
| User entered 'No (N)'   | (b) (4), (b) (6)                      | 11 Aug 2020 16:15:08 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:20:34**

[Indication](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| User signature succeeded.     | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.           | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:37:25 |
| User entered 'GENERAL HEALTH' | (b) (4), (b) (6)            | 11 Aug 2020 16:15:08 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| User closed query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified.  | (b) (4), (b) (6)           | 23 Apr 2021 21:42:48 |
|   |                            | 23 Apr 2021 21:42:47 |
| Query 'Con med source yet to be updated. Please reconcile. ' answered with 'updated' (Site from CRA).   |                            | 23 Apr 2021 21:36:59 |
| User opened query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).   |                            | 23 Apr 2021 14:14:30 |
| User closed query 'Please provide updated dose in con med source' (Site from CRA).  |                            | 23 Apr 2021 14:14:30 |
| User signature succeeded.   | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
|   | (b) (4)                    |                      |
| Query 'Please provide updated dose in con med source' answered with 'updated' (Site from CRA).  | Victoria Hernandez (b) (4) | 12 Mar 2021 19:19:00 |
| User opened query 'Please provide updated dose in con med source' (Site from CRA).  | (b) (4)                    |                      |
|   | (b) (4), (b) (6)           | 10 Mar 2021 17:36:54 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. | (b) (4), (b) (6)           | 29 Sep 2020 13:55:50 |
| ' (Site from DM).   |                            |                      |
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.             | Victoria Hernandez (b) (4) | 17 Sep 2020 17:23:10 |
| ' answered with 'UPDATED PER SUBJECT' (Site from DM).   | (b) (4)                    |                      |
| User entered '600' reason for change: New Information   | Victoria Hernandez (b) (4) | 17 Sep 2020 17:22:55 |
|   | (b) (4)                    |                      |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. | (b) (4), (b) (6)           | 17 Sep 2020 11:50:37 |
| ' (Site from DM).   |                            |                      |
| User entered 'I'  | (b) (4), (b) (6)           | 11 Aug 2020 16:15:08 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| User closed query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified. | (b) (4), (b) (6)           | 23 Apr 2021 21:42:52 |
|  |                            | 23 Apr 2021 21:42:50 |
| Query 'Con med source yet to be updated. Please reconcile. ' answered with 'updated' (Site from CRA).            |                            | 23 Apr 2021 21:37:04 |
| User opened query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).                        |                            | 23 Apr 2021 14:14:38 |
| User closed query 'Please provide updated dose in con med source' (Site from CRA).                               |                            | 23 Apr 2021 14:14:38 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
|  | (b) (4)                    |                      |
| Query 'Please provide updated dose in con med source' answered with 'updated' (Site from CRA).                   | Victoria Hernandez (b) (4) | 12 Mar 2021 19:19:07 |
|  | (b) (4)                    |                      |
| User opened query 'Please provide updated dose in con med source' (Site from CRA).                               | (b) (4), (b) (6)           | 10 Mar 2021 17:37:00 |
|  |                            |                      |
| User entered 'mg (mg)' reason for change: New Information  | Victoria Hernandez (b) (4) | 17 Sep 2020 17:22:55 |
|  | (b) (4)                    |                      |
| User entered 'tablet (TABLET)'   | (b) (4), (b) (6)           | 11 Aug 2020 16:15:08 |
|  |                            |                      |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:20:34**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:37:29 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:15:08 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)                |                      |
|                                | (b) (4), (b) (6)       | 10 Mar 2021 17:37:31 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)       | 11 Aug 2020 16:15:08 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:20:34

If frequency is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:37:38 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:15:08 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:20:34

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:37:41 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:15:08 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:20:34

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:37:44 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:15:08 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:38:59 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:11:38 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:15:11 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:15:08 |
| User entered 'UN UNK 2015'   | (b) (4), (b) (6)       | 11 Aug 2020 16:15:08 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:38:55 |
| User entered '0'          | (b) (4), (b) (6)            | 11 Aug 2020 16:15:08 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:39:04 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:15:08 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:39:08 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:15:08 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:39:17 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:15:08 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:15:08 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:15:08 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:15:08 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)                |                      |
|   | (b) (4), (b) (6)       | 10 Mar 2021 17:39:35 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B NOS - version WHODrug-Global-B3\\202003.                                | Coder Import (b) (4)   | 13 Oct 2020 13:28:58 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)   | 13 Oct 2020 13:28:58 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: VITAMIN B - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 11 Aug 2020 16:17:09 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)   | 11 Aug 2020 16:17:09 |
| Data point term sent to Coder   | System                 | 11 Aug 2020 16:16:05 |
| User entered 'Vitamin b'  | (b) (4), (b) (6)       | 11 Aug 2020 16:15:44 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:20:34

[Prophylaxis](#)

| Audit   | User                                  | Time (GMT)           |
|---|---------------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)                | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)           | 10 Mar 2021 17:40:09 |
| User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).             | (b) (4), (b) (6)                      | 19 Jan 2021 20:51:32 |
| Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM). | Victoria Hernandez (b) (4)<br>(b) (4) | 19 Jan 2021 16:40:30 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Victoria Hernandez (b) (4)<br>(b) (4) | 19 Jan 2021 16:40:25 |
| User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).             | (b) (4), (b) (6)                      | 19 Jan 2021 13:43:17 |
| User entered 'No (N)'   | (b) (4), (b) (6)                      | 11 Aug 2020 16:15:44 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:20:34**

[Indication](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| User signature succeeded.     | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.           | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:40:17 |
| User entered 'General health' | (b) (4), (b) (6)            | 11 Aug 2020 16:15:44 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| User closed query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified.  | (b) (4), (b) (6)           | 23 Apr 2021 21:43:02 |
|   |                            | 23 Apr 2021 21:43:01 |
| Query 'Con med source yet to be updated. Please reconcile. ' answered with 'updated' (Site from CRA).   |                            | 23 Apr 2021 21:37:55 |
| User opened query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).   |                            | 23 Apr 2021 14:14:47 |
| User closed query 'Please provide updated dose in con med source' (Site from CRA).  |                            | 23 Apr 2021 14:14:47 |
| User signature succeeded.   | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
|   | (b) (4)                    |                      |
| Query 'Please provide updated dose in con med source' answered with 'updated' (Site from CRA).  | Victoria Hernandez (b) (4) | 12 Mar 2021 19:19:35 |
| User opened query 'Please provide updated dose in con med source' (Site from CRA).  | (b) (4)                    |                      |
|   | (b) (4), (b) (6)           | 10 Mar 2021 17:39:49 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. | (b) (4), (b) (6)           | 29 Sep 2020 13:56:40 |
| ' (Site from DM).   |                            |                      |
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.             | Victoria Hernandez (b) (4) | 17 Sep 2020 17:24:37 |
| ' answered with 'UPDATED PER SUBJECT' (Site from DM).   | (b) (4)                    |                      |
| User entered '1000' reason for change: New Information  | Victoria Hernandez (b) (4) | 17 Sep 2020 17:24:21 |
|   | (b) (4)                    |                      |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. | (b) (4), (b) (6)           | 17 Sep 2020 11:52:02 |
| ' (Site from DM).   |                            |                      |
| User entered 'I'  | (b) (4), (b) (6)           | 11 Aug 2020 16:15:44 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| User closed query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).<br>DataPoint Verified.   | (b) (4), (b) (6)           | 23 Apr 2021 21:43:06 |
|  |                            | 23 Apr 2021 21:43:04 |
| Query 'Con med source yet to be updated. Please reconcile. ' answered with 'updated' (Site from CRA).  |                            | 23 Apr 2021 21:37:59 |
| User opened query 'Con med source yet to be updated. Please reconcile. ' (Site from CRA).  |                            | 23 Apr 2021 14:14:50 |
| User closed query 'Please provide updated dose in con med source' (Site from CRA).   |                            | 23 Apr 2021 14:14:50 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
|  | (b) (4)                    |                      |
| User closed query 'Per CDM: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate (e.g: ug).' (Site from DM).  | (b) (4), (b) (6)           | 15 Mar 2021 11:29:44 |
| Query 'Please provide updated dose in con med source' answered with 'updated' (Site from CRA).   | Victoria Hernandez (b) (4) | 12 Mar 2021 19:20:00 |
|  | (b) (4)                    |                      |
| Query 'Per CDM: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate (e.g: ug).' answered with 'correct as is' (Site from DM).  | Victoria Hernandez (b) (4) | 12 Mar 2021 19:19:51 |
|  | (b) (4)                    |                      |
| User opened query 'Please provide updated dose in con med source' (Site from CRA).   | (b) (4), (b) (6)           | 10 Mar 2021 17:40:02 |
| User opened query 'Per CDM: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate (e.g: ug).' (Site from DM).  | (b) (4), (b) (6)           | 02 Mar 2021 10:12:52 |
| 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).                                |                            | 02 Mar 2021 10:11:27 |
| 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 'correct as is per subject ' (Site from DM). | Victoria Hernandez (b) (4) | 01 Mar 2021 16:36:46 |
|  | (b) (4)                    |                      |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| 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)           | 21 Feb 2021 09:51:32 |
| User entered 'mg (mg)' reason for change: New Information   | Victoria Hernandez (b) (4) | 17 Sep 2020 17:24:21 |
| User entered 'tablet (TABLET)'  | (b) (4), (b) (6)           | 11 Aug 2020 16:15:44 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:40:36 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:15:44 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:40:37 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 11 Aug 2020 16:15:44 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:20:34

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:40:41 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:15:44 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:20:34

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:40:48 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:15:44 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:20:34**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:40:51 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:15:44 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:40:55 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:11:44 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:15:49 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:15:44 |
| User entered 'un UNK 2015'   | (b) (4), (b) (6)       | 11 Aug 2020 16:15:44 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:41:02 |
| User entered '0'          | (b) (4), (b) (6)            | 11 Aug 2020 16:15:44 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:41:05 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:15:44 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:41:08 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:15:44 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:41:14 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 11 Aug 2020 16:15:44 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:15:44 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:15:44 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:15:44 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 10 Mar 2021 17:42:10 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: BETA<br>BLOCKING AGENTS, ATC: BETA BLOCKING<br>AGENTS, ATC: BETA BLOCKING AGENTS,<br>SELECTIVE, PRODUCT: METOPROLOL -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 16:18:13 |
| 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) | 11 Aug 2020 16:18:13 |
| Data point term sent to Coder  | System                          | 11 Aug 2020 16:17:11 |
| User entered 'Metoprolol'  | (b) (4), (b) (6)                | 11 Aug 2020 16:16:34 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:20:34

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:42:15 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 11 Aug 2020 16:16:34 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit                       | User                   | Time (GMT)           |
|-----------------------------|------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.         | (b) (4)                |                      |
|                             | (b) (4), (b) (6)       | 10 Mar 2021 17:42:20 |
| User entered 'hypertension' | (b) (4), (b) (6)       | 11 Aug 2020 16:16:34 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
| User closed query 'Per source, value is 20.' (Site from CRA).             | (b) (4), (b) (6)           | 23 Mar 2021 15:25:10 |
| DataPoint Verified.   | (b) (4), (b) (6)           | 23 Mar 2021 15:25:09 |
| Query 'Per source, value is 20.' answered with 'updated' (Site from CRA). | Victoria Hernandez (b) (4) | 12 Mar 2021 19:20:31 |
| User entered '20' reason for change: Data Entry Error                     | Victoria Hernandez (b) (4) | 12 Mar 2021 19:20:22 |
| User opened query 'Per source, value is 20.' (Site from CRA).             | (b) (4), (b) (6)           | 10 Mar 2021 17:42:06 |
| User entered '25'   | (b) (4), (b) (6)           | 11 Aug 2020 16:16:34 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:42:39 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:16:34 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:42:44 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:16:34 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:42:48 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 11 Aug 2020 16:16:34 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:20:34

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:42:58 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:16:34 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:20:34**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:43:02 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:16:34 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:20:34

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:43:10 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:16:34 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:43:23 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:11:50 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:16:41 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:16:34 |
| User entered 'un UNK 2005'   | (b) (4), (b) (6)       | 11 Aug 2020 16:16:34 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:20:34

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:43:26 |
| User entered '0'          | (b) (4), (b) (6)            | 11 Aug 2020 16:16:34 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:44:31 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:16:34 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:20:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:44:38 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:16:34 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:44:58 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:16:34 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:16:34 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:16:34 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:16:34 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 10 Mar 2021 17:49:23 |
| 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) | 11 Aug 2020 16:19:09 |
| 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) | 11 Aug 2020 16:19:09 |
| Data point term sent to Coder  | System                          | 11 Aug 2020 16:18:12 |
| User entered 'amlodipine'  | (b) (4), (b) (6)                | 11 Aug 2020 16:17:17 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:49:25 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 11 Aug 2020 16:17:17 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit                       | User                        | Time (GMT)           |
|-----------------------------|-----------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.         | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:49:29 |
| User entered 'hypertension' | (b) (4), (b) (6)            | 11 Aug 2020 16:17:17 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:49:32 |
| User entered '10'         | (b) (4), (b) (6)            | 11 Aug 2020 16:17:17 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:49:34 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:17:17 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:49:36 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:17:17 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:49:38 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 11 Aug 2020 16:17:17 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:49:42 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:17:17 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:49:43 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:17:17 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:49:45 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:17:17 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:49:48 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:11:56 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:17:22 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:17:17 |
| User entered 'un UNK 2005'   | (b) (4), (b) (6)       | 11 Aug 2020 16:17:17 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:49:49 |
| User entered '0'          | (b) (4), (b) (6)            | 11 Aug 2020 16:17:17 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:49:52 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:17:17 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:49:56 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:17:17 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:49:58 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:17:17 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:17:17 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:17:17 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:17:17 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 10 Mar 2021 17:50:12 |
| 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: ATORVASTATIN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 16:19:10 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 16:19:10 |
| Data point term sent to Coder  | System                          | 11 Aug 2020 16:18:13 |
| User entered 'atorvastatin'  | (b) (4), (b) (6)                | 11 Aug 2020 16:18:00 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:20:34**

[Prophylaxis](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:50:14 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:18:00 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:20:34**

[Indication](#)

| Audit                               | User                        | Time (GMT)           |
|-------------------------------------|-----------------------------|----------------------|
| User signature succeeded.           | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.                 | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:50:15 |
| User entered 'hypercholesterolemia' | (b) (4), (b) (6)            | 11 Aug 2020 16:18:00 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:50:17 |
| User entered '40'         | (b) (4), (b) (6)       | 11 Aug 2020 16:18:00 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:50:19 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)       | 11 Aug 2020 16:18:00 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:50:21 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:18:00 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:50:23 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 11 Aug 2020 16:18:00 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:20:34

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:50:27 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:18:00 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:20:34

[Route of administration](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)                |                      |
|                            | (b) (4), (b) (6)       | 10 Mar 2021 17:50:29 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)       | 11 Aug 2020 16:18:00 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:20:34

If route of administration is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:50:31 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:18:00 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:50:32 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).    | (b) (4), (b) (6)       | 12 Aug 2020 13:10:31 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:18:00 |
| User entered 'un UNK 2015'   | (b) (4), (b) (6)       | 11 Aug 2020 16:18:00 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:20:34

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:50:34 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:18:00 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:50:35 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:18:00 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:50:37 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:18:00 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:50:39 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:18:00 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:18:00 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:18:00 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:18:00 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 10 Mar 2021 17:50:46 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: AGENTS<br>ACTING ON THE RENIN-ANGIOTENSIN<br>SYSTEM, ATC: ANGIOTENSIN II RECEPTOR<br>BLOCKERS (ARBS), PLAIN, ATC:<br>ANGIOTENSIN II RECEPTOR BLOCKERS<br>(ARBS), PLAIN, PRODUCT: LOSARTAN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 17 Aug 2020 08:37:20 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 17 Aug 2020 08:37:20 |
| Data point term sent to Coder  | System                          | 11 Aug 2020 16:19:14 |
| User entered 'lostartan'   | (b) (4), (b) (6)                | 11 Aug 2020 16:18:35 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:50:48 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 11 Aug 2020 16:18:35 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit                       | User                   | Time (GMT)           |
|-----------------------------|------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.         | (b) (4)                |                      |
|                             | (b) (4), (b) (6)       | 10 Mar 2021 17:50:53 |
| User entered 'hypertension' | (b) (4), (b) (6)       | 11 Aug 2020 16:18:35 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:50:58 |
| User entered '100'        | (b) (4), (b) (6)            | 11 Aug 2020 16:18:35 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:51:02 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:18:35 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:51:04 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:18:35 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:51:05 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 11 Aug 2020 16:18:35 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

If frequency is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:51:08 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:18:35 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:20:34**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:51:11 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:18:35 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:51:14 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:18:35 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:51:19 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:12:10 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:18:38 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:18:35 |
| User entered 'un UNK 2005'   | (b) (4), (b) (6)       | 11 Aug 2020 16:18:35 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:51:23 |
| User entered '0'          | (b) (4), (b) (6)            | 11 Aug 2020 16:18:35 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:51:25 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:18:35 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:51:28 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:18:35 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:51:33 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:18:35 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:18:35 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:18:35 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:18:35 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 10 Mar 2021 17:52:30 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: THYROID, PRODUCTSYNONYM: ARMOUR THYROID - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 22:06:12 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.   | Coder Import (b) (4)<br>(b) (4) | 11 Aug 2020 22:06:12 |
| Data point term sent to Coder   | System                          | 11 Aug 2020 16:20:15 |
| User entered 'armour thyroid'   | (b) (4), (b) (6)                | 11 Aug 2020 16:19:39 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:20:34**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:52:32 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 11 Aug 2020 16:19:39 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:52:34 |
| User entered 'hypothyroid' | (b) (4), (b) (6)            | 11 Aug 2020 16:19:39 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:52:42 |
| User entered '60'         | (b) (4), (b) (6)            | 11 Aug 2020 16:19:39 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)                    |                      |
|   | (b) (4), (b) (6)           | 23 Mar 2021 15:25:43 |
| User closed query 'Per source, Dose unit is ug. Please review and reconcile, ' (Site from CRA).                   | (b) (4), (b) (6)           | 23 Mar 2021 15:25:41 |
| Query 'Per source, Dose unit is ug. Please review and reconcile, ' answered with 'correct as is' (Site from CRA). | Victoria Hernandez (b) (4) | 12 Mar 2021 19:21:42 |
|   | (b) (4)                    |                      |
| User opened query 'Per source, Dose unit is ug. Please review and reconcile, ' (Site from CRA).                   | (b) (4), (b) (6)           | 10 Mar 2021 17:52:26 |
| User entered 'ug (ug)'  | (b) (4), (b) (6)           | 11 Aug 2020 16:19:39 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:52:44 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:19:39 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:52:47 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 11 Aug 2020 16:19:39 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:20:34

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:52:48 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:19:39 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:20:34

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:52:50 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:19:39 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:20:34

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:52:51 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:19:39 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:52:56 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:12:16 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:19:41 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:19:39 |
| User entered 'un UNK 2015'   | (b) (4), (b) (6)       | 11 Aug 2020 16:19:39 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:52:58 |
| User entered '0'          | (b) (4), (b) (6)       | 11 Aug 2020 16:19:39 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:53:17 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:19:39 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:20:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:53:19 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:19:39 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:53:21 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 11 Aug 2020 16:19:39 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:19:39 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:19:39 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:19:39 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 10 Mar 2021 17:53:30 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 12 Aug 2020 18:11:16 |
| 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 Aug 2020 18:11:16 |
| Data point term sent to Coder   | System                          | 11 Aug 2020 16:20:15 |
| User entered 'progesterone'   | (b) (4), (b) (6)                | 11 Aug 2020 16:20:14 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:20:34**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:53:32 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 11 Aug 2020 16:20:14 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit                           | User                        | Time (GMT)           |
|---------------------------------|-----------------------------|----------------------|
| User signature succeeded.       | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.             | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:53:35 |
| User entered 'low progesterone' | (b) (4), (b) (6)            | 11 Aug 2020 16:20:14 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:20:34**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:53:37 |
| User entered '200'        | (b) (4), (b) (6)            | 11 Aug 2020 16:20:14 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:53:40 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:20:14 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:53:43 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:20:14 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:53:52 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 11 Aug 2020 16:20:14 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:20:34

If frequency is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:53:54 |
| User entered empty.       | (b) (4), (b) (6)       | 11 Aug 2020 16:20:14 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:20:34**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:53:58 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:20:14 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:20:34

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:54:03 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:20:14 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:54:09 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:12:28 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:20:17 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:20:14 |
| User entered 'un UNK 2015'   | (b) (4), (b) (6)       | 11 Aug 2020 16:20:14 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:20:34

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:54:11 |
| User entered '0'          | (b) (4), (b) (6)            | 11 Aug 2020 16:20:14 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:54:13 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:20:14 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:20:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:54:17 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:20:14 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:54:20 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:20:14 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:20:14 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:20:14 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:20:14 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 10 Mar 2021 17:54:30 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 15 Sep 2020 19:15:55 |
| 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) | 15 Sep 2020 19:15:55 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 13 Aug 2020 12:50:23 |
| 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) | 13 Aug 2020 12:50:23 |
| Data point term sent to Coder  | System                          | 11 Aug 2020 16:21:16 |
| User entered 'Nexium'  | (b) (4), (b) (6)                | 11 Aug 2020 16:20:47 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:20:34**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:54:33 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 11 Aug 2020 16:20:47 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:20:34**

[Indication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:54:41 |
| User entered 'GERD'       | (b) (4), (b) (6)            | 11 Aug 2020 16:20:47 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:20:34**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:54:46 |
| User entered '40'         | (b) (4), (b) (6)            | 11 Aug 2020 16:20:47 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:54:53 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:20:47 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:54:55 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:20:47 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:54:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)            | 11 Aug 2020 16:20:47 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:20:34

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:54:58 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:20:47 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:20:34

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:55:02 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)            | 11 Aug 2020 16:20:47 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:20:34**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:55:05 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:20:47 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 10 Mar 2021 17:55:09 |
| User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | (b) (4), (b) (6)       | 12 Aug 2020 16:12:34 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'                                 | (b) (4), (b) (6)       | 11 Aug 2020 16:20:49 |
| answered with 'Medication is ongoing, correct as entered' (Site from System).  |                        |                      |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System                 | 11 Aug 2020 16:20:47 |
| User entered 'un UNK 2000'   | (b) (4), (b) (6)       | 11 Aug 2020 16:20:47 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:20:34

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:55:11 |
| User entered '0'          | (b) (4), (b) (6)            | 11 Aug 2020 16:20:47 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:55:13 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 11 Aug 2020 16:20:47 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:55:16 |
| User entered empty.       | (b) (4), (b) (6)            | 11 Aug 2020 16:20:47 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 10 Mar 2021 17:55:20 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 11 Aug 2020 16:20:47 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 11 Aug 2020 16:20:47 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 11 Aug 2020 16:20:47 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 16:20:47 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 01 May 2021 21:29:52 |
| User signature succeeded.   | Douglas Denham (b) (4)          | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 10 Mar 2021 17:58:27 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANTIEPILEPTICS, ATC:<br>ANTIEPILEPTICS, ATC: OTHER<br>ANTIEPILEPTICS, PRODUCT:<br>LEVETIRACETAM, PRODUCTSYNONYM:<br>KEPPRA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 20 Nov 2020 22:18:04 |
| 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) | 20 Nov 2020 22:18:04 |
| Data point term sent to Coder   | System                          | 20 Nov 2020 22:16:47 |
| User entered 'Keppra'   | Antonio Gutierrez (b) (4)       | 20 Nov 2020 22:16:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:20:34

[Prophylaxis](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 01 May 2021 21:29:52 |
| User signature succeeded. | Douglas Denham (b) (4)    | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4), (b) (6)          | 10 Mar 2021 17:58:29 |
| User entered 'Yes (Y)'    | Antonio Gutierrez (b) (4) | 20 Nov 2020 22:16:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 01 May 2021 21:29:52 |
| User signature succeeded.                                     | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:58:31 |
| User entered 'Seizure prevention following subdural hematoma' | Antonio Gutierrez (b) (4)   | 20 Nov 2020 22:16:43 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:20:34**

[Dose per administration](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 01 May 2021 21:29:52 |
| User signature succeeded. | Douglas Denham (b) (4)    | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4), (b) (6)          | 10 Mar 2021 17:58:33 |
| User entered '750'        | Antonio Gutierrez (b) (4) | 20 Nov 2020 22:16:43 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:20:34**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 21:29:52 |
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:58:35 |
| User entered 'mg (mg)'    | Antonio Gutierrez (b) (4)   | 20 Nov 2020 22:16:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 01 May 2021 21:29:52 |
| User signature succeeded. | Douglas Denham (b) (4)    | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4), (b) (6)          | 10 Mar 2021 17:58:36 |
| User entered empty.       | Antonio Gutierrez (b) (4) | 20 Nov 2020 22:16:43 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:20:34**

[Frequency](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 01 May 2021 21:29:52 |
| User signature succeeded.        | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:58:38 |
| User entered 'twice daily (BID)' | Antonio Gutierrez (b) (4)   | 20 Nov 2020 22:16:43 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:20:34**

[If frequency is Other, specify](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 01 May 2021 21:29:52 |
| User signature succeeded. | Douglas Denham (b) (4)    | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4), (b) (6)          | 10 Mar 2021 17:58:39 |
| User entered empty.       | Antonio Gutierrez (b) (4) | 20 Nov 2020 22:16:43 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:20:34**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 21:29:52 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 17:58:41 |
| User entered 'Oral (ORAL)' | Antonio Gutierrez (b) (4)   | 20 Nov 2020 22:16:43 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:20:34**

[If route of administration is Other, specify](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 01 May 2021 21:29:52 |
| User signature succeeded. | Douglas Denham (b) (4)    | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4), (b) (6)          | 10 Mar 2021 17:58:44 |
| User entered empty.       | Antonio Gutierrez (b) (4) | 20 Nov 2020 22:16:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:20:34

Start date (dd MMM yyyy)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 01 May 2021 21:29:52 |
| User signature succeeded.   | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
| User closed query 'Per source, Start date is 14Nov2020. please reconcile.' (Site from CRA).             | (b) (4)                    |                      |
| DataPoint Verified.   | (b) (4), (b) (6)           | 23 Mar 2021 15:26:58 |
|   | (b) (4), (b) (6)           | 23 Mar 2021 15:26:53 |
| Query 'Per source, Start date is 14Nov2020. please reconcile.' answered with 'updated' (Site from CRA). | Victoria Hernandez (b) (4) | 12 Mar 2021 19:23:14 |
| User entered '14 Nov 2020' reason for change: Data Entry Error  | (b) (4)                    |                      |
| User opened query 'Per source, Start date is 14Nov2020. please reconcile.' (Site from CRA).             | Victoria Hernandez (b) (4) | 12 Mar 2021 19:23:05 |
| User entered '15 Nov 2020'  | (b) (4)                    |                      |
|   | (b) (4), (b) (6)           | 10 Mar 2021 17:56:47 |
|   | Antonio Gutierrez (b) (4)  | 20 Nov 2020 22:16:43 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:20:34

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 21:29:52 |
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 23 Mar 2021 15:26:59 |
| User entered '0'          | Antonio Gutierrez (b) (4)   | 20 Nov 2020 22:16:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:20:34

[Ongoing?](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)           | 01 May 2021 21:29:52 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
| User closed query 'Per source, end date is 22Nov2020' (Site from CRA).             | (b) (4)                    |                      |
| DataPoint Verified.  | (b) (4), (b) (6)           | 23 Mar 2021 15:27:02 |
|  | (b) (4), (b) (6)           | 23 Mar 2021 15:27:01 |
| Query 'Per source, end date is 22Nov2020' answered with 'updated' (Site from CRA). | Victoria Hernandez (b) (4) | 12 Mar 2021 19:23:24 |
| User entered 'No (N)' reason for change: Data Entry Error                          | (b) (4)                    |                      |
|  | Victoria Hernandez (b) (4) | 12 Mar 2021 19:23:05 |
| User opened query 'Per source, end date is 22Nov2020' (Site from CRA).             | (b) (4), (b) (6)           | 10 Mar 2021 17:57:11 |
| User entered 'Yes (Y)'   | Antonio Gutierrez (b) (4)  | 20 Nov 2020 22:16:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:20:34

If not Ongoing, End date (dd MMM yyyy)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)           | 01 May 2021 21:29:52 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 16 Apr 2021 14:02:04 |
| User closed query 'Per source, end date is 22Nov2020' (Site from CRA).             | (b) (4)                    |                      |
| DataPoint Verified.  | (b) (4), (b) (6)           | 23 Mar 2021 15:27:05 |
|  | (b) (4), (b) (6)           | 23 Mar 2021 15:27:03 |
| Query 'Per source, end date is 22Nov2020' answered with 'updated' (Site from CRA). | Victoria Hernandez (b) (4) | 12 Mar 2021 19:23:32 |
| User entered '22 Nov 2020' reason for change: Data Entry Error                     | (b) (4)                    |                      |
| User opened query 'Per source, end date is 22Nov2020' (Site from CRA).             | Victoria Hernandez (b) (4) | 12 Mar 2021 19:23:05 |
|  | (b) (4), (b) (6)           | 10 Mar 2021 17:58:25 |
| User entered empty.  | Antonio Gutierrez (b) (4)  | 20 Nov 2020 22:16:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                      | Time (GMT)           |
|---------------------------|---------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)          | 01 May 2021 21:29:52 |
| User signature succeeded. | Douglas Denham (b) (4)    | 16 Apr 2021 14:02:04 |
| DataPoint Verified.       | (b) (4), (b) (6)          | 23 Mar 2021 15:27:08 |
| User entered 'No (N)'     | Antonio Gutierrez (b) (4) | 20 Nov 2020 22:16:43 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:29:52 |
| User entered '2'  | System           | 20 Nov 2020 22:16:43 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 21:29:52 |
| User entered 'I'  | System           | 20 Nov 2020 22:16:43 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 01 May 2021 21:29:52 |
| User entered '804 (804)' | System           | 20 Nov 2020 22:16:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 01 May 2021 21:29:58 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 23 Apr 2021 14:15:31 |
| User signature succeeded.   | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 31 Mar 2021 14:08:33 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)   | 31 Mar 2021 14:08:33 |
| Data point term sent to Coder   | System                 | 23 Mar 2021 18:35:03 |
| User entered 'Influenza Vaccine'  | Dawn Killian (b) (4)   | 23 Mar 2021 18:34:27 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:20:34

[Prophylaxis](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:29:58 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:15:31 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'Yes (Y)'    | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:34:27 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:20:34**

[Indication](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| Data hard locked.                             | (b) (4), (b) (6)                           | 01 May 2021 21:29:58 |
| DataPoint Verified.                           | (b) (4), (b) (6)                           | 23 Apr 2021 14:15:31 |
| User signature succeeded.                     | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'Prophylaxis for flu prevention' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:34:27 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:29:58 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:15:31 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '0.5'        | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:34:27 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:29:58 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:15:31 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'mL (mL)'    | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:34:27 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:20:34**

[If dose unit is Other, specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:29:58 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:15:31 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:34:27 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 01 May 2021 21:29:58 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 23 Apr 2021 14:15:31 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'once (ONCE)' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:34:27 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:20:34

If frequency is Other, specify

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:29:58 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:15:31 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:34:27 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:20:34

[Route of administration](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                           | 01 May 2021 21:29:58 |
| DataPoint Verified.                          | (b) (4), (b) (6)                           | 23 Apr 2021 14:15:31 |
| User signature succeeded.                    | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:34:27 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:20:34

If route of administration is Other, specify

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:29:58 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:15:31 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:34:27 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 01 May 2021 21:29:58 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 23 Apr 2021 14:15:31 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '06 Oct 2020' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:34:27 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:29:58 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:15:31 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '0'          | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:34:27 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:29:58 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:15:31 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'No (N)'     | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:34:27 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:20:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 01 May 2021 21:29:58 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 23 Apr 2021 14:15:31 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '06 Oct 2020' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:34:27 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 01 May 2021 21:29:58 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 23 Apr 2021 14:15:31 |
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)                |                      |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 23 Mar 2021 18:35:55 |
| User entered 'No (N)' reason for change: Data Entry Error                              | System                 | 23 Mar 2021 18:35:55 |
| User opened query 'Data is required. Please complete.' (Site from System).             | Dawn Killian (b) (4)   | 23 Mar 2021 18:35:55 |
| User entered empty.  | (b) (4)                |                      |
|  | System                 | 23 Mar 2021 18:34:27 |
|  | Dawn Killian (b) (4)   | 23 Mar 2021 18:34:27 |
|  | (b) (4)                |                      |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:20:34**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 21:29:58 |
| User entered empty. | System           | 23 Mar 2021 18:34:27 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 21:29:58 |
| User entered empty. | System           | 23 Mar 2021 18:34:27 |



US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 21:29:58 |
| User entered empty. | System           | 23 Mar 2021 18:34:27 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 01 May 2021 21:30:03 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 23 Apr 2021 14:17:33 |
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 12 Apr 2021 19:46:50 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)   | 12 Apr 2021 19:46:50 |
| Data point term sent to Coder  | System                 | 12 Apr 2021 18:35:42 |
| Data point term sent to Coder  | System                 | 12 Apr 2021 18:34:39 |
| Coding entries removed.  | Kristy Trevino (b) (4) | 12 Apr 2021 18:34:15 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 23 Mar 2021 18:35:48 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)   | 23 Mar 2021 18:35:48 |
| Data point term sent to Coder  | System                 | 23 Mar 2021 18:35:13 |
| User entered 'Pneumovax'   | Dawn Killian (b) (4)   | 23 Mar 2021 18:35:09 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:20:34**

[Prophylaxis](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:03 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:33 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'Yes (Y)'    | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:09 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 01 May 2021 21:30:03 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 23 Apr 2021 14:17:33 |
| User signature succeeded.   | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User closed query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented. Update Con Med eCRF as appropriate.<br>' (Site from DM).             | (b) (4), (b) (6)       | 14 Apr 2021 09:04:54 |
| Query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented. Update Con Med eCRF as appropriate.<br>' answered with 'updated' (Site from DM). | Kristy Trevino (b) (4) | 12 Apr 2021 18:35:41 |
| User entered 'Vaccine for Pneumonia' reason for change: Data Entry Error  | (b) (4)                | 12 Apr 2021 18:35:14 |
| User entered 'Vaccine' reason for change: Data Entry Error  | Kristy Trevino (b) (4) | 12 Apr 2021 18:34:15 |
| User opened query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented. Update Con Med eCRF as appropriate.<br>' (Site from DM).             | (b) (4), (b) (6)       | 05 Apr 2021 13:46:41 |
| User entered 'prophylaxis'  | Dawn Killian (b) (4)   | 23 Mar 2021 18:35:09 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:03 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:33 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '0.5'        | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:09 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:03 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:33 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'mL (mL)'    | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:09 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:03 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:33 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:09 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 01 May 2021 21:30:03 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:33 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'once (ONCE)' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:09 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:20:34**

[If frequency is Other, specify](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:03 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:33 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:09 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:20:34

[Route of administration](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                           | 01 May 2021 21:30:03 |
| DataPoint Verified.                          | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:33 |
| User signature succeeded.                    | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:09 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:20:34

If route of administration is Other, specify

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:03 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:33 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:09 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 01 May 2021 21:30:03 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:33 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '16 Dec 2020' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:09 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:03 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:33 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '0'          | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:09 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:20:34

[Ongoing?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:03 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:33 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'No (N)'     | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:09 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:20:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 01 May 2021 21:30:03 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:33 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '16 Dec 2020' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:09 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:20:34

[Was this medication taken for solicited event?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:03 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:33 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'No (N)'     | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:09 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:20:34

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 21:30:03 |
| User entered empty. | System           | 23 Mar 2021 18:35:09 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 21:30:03 |
| User entered empty. | System           | 23 Mar 2021 18:35:09 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 21:30:03 |
| User entered empty. | System           | 23 Mar 2021 18:35:09 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:20:34

[Name of Medication](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 01 May 2021 21:30:04 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 23 Apr 2021 14:17:50 |
| User signature succeeded.   | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: TETANUS VACCINES, PRODUCT: TETANUS VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 14 Apr 2021 08:45:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)   | 14 Apr 2021 08:45:41 |
| Data point term sent to Coder   | System                 | 12 Apr 2021 18:38:48 |
| Coding entries removed.   | Kristy Trevino (b) (4) | 12 Apr 2021 18:38:41 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: TETANUS VACCINES, PRODUCT: TETANUS VACCINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)   | 23 Mar 2021 18:51:51 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)   | 23 Mar 2021 18:51:51 |
| Data point term sent to Coder   | System                 | 23 Mar 2021 18:36:14 |
| User entered 'Tetanus Shot'   | Dawn Killian (b) (4)   | 23 Mar 2021 18:35:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:20:34

[Prophylaxis](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:04 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:50 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'Yes (Y)'    | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 01 May 2021 21:30:04 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 23 Apr 2021 14:17:50 |
| User signature succeeded.   | Douglas Denham (b) (4) | 16 Apr 2021 14:02:04 |
| User closed query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented. Update Con Med eCRF as appropriate.<br>' (Site from DM).             | (b) (4), (b) (6)       | 14 Apr 2021 09:05:12 |
| Query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented. Update Con Med eCRF as appropriate.<br>' answered with 'updated' (Site from DM). | Kristy Trevino (b) (4) | 12 Apr 2021 18:39:10 |
| User entered 'Vaccine for Tetanus' reason for change: Data Entry Error  | (b) (4)                |                      |
| User opened query 'Per DM CLR: Please update the indication of this medication to include the medical condition being prevented. Update Con Med eCRF as appropriate.<br>' (Site from DM).             | Kristy Trevino (b) (4) | 12 Apr 2021 18:38:41 |
| User entered 'prophylaxis'  | (b) (4), (b) (6)       | 05 Apr 2021 13:47:13 |
|   | Dawn Killian (b) (4)   | 23 Mar 2021 18:35:43 |
|   | (b) (4)                |                      |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:20:34

[Dose per administration](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:04 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:50 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '0.5'        | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:20:34

[Dose unit](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:04 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:50 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'mL (mL)'    | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:43 |



US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:20:34

If dose unit is Other, specify

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:04 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:50 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:20:34

[Frequency](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 01 May 2021 21:30:04 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:50 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'once (ONCE)' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:20:34

If frequency is Other, specify

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:04 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:50 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:43 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:20:34**

[Route of administration](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)                           | 01 May 2021 21:30:04 |
| DataPoint Verified.                          | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:50 |
| User signature succeeded.                    | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:43 |

US3292103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:20:34

If route of administration is Other, specify

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:04 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:50 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered empty.       | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:43 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 01 May 2021 21:30:04 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:50 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '15 Nov 2020' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:43 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:20:34**

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:04 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:50 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '0'          | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:43 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:20:34**

[Ongoing?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:04 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:50 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'No (N)'     | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:43 |



**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:20:34**

**If not Ongoing, End date** (*dd MMM yyyy*)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 01 May 2021 21:30:04 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:50 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered '15 Nov 2020' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:43 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:20:34**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 01 May 2021 21:30:04 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 23 Apr 2021 14:17:50 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 16 Apr 2021 14:02:04 |
| User entered 'No (N)'     | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 23 Mar 2021 18:35:43 |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:20:34

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 21:30:04 |
| User entered empty. | System           | 23 Mar 2021 18:35:43 |

US3292103

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 21:30:04 |
| User entered empty. | System           | 23 Mar 2021 18:35:43 |

**US3292103**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 16:20:34**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 21:30:04 |
| User entered empty. | System           | 23 Mar 2021 18:35:43 |

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:20:34

[Were any concomitant procedures performed?](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                     | 03 May 2021 05:13:16 |
| DataPoint Verified.       | (b) (4), (b) (6)                     | 10 Mar 2021 18:06:26 |
| User signature succeeded. | Douglas Denham (b) (4)               | 22 Feb 2021 18:45:07 |
| User entered 'Yes (Y)'    | (b) (4)<br>Antonio Gutierrez (b) (4) | 20 Nov 2020 22:14:09 |

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:20:34

Procedure/Surgery date (*dd MMM yyyy*)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                     | 10 Mar 2021 18:07:05 |
| User signature succeeded.  | Douglas Denham (b) (4)               | 22 Feb 2021 18:45:07 |
| User entered '15 Nov 2020' | (b) (4)<br>Antonio Gutierrez (b) (4) | 20 Nov 2020 22:14:29 |

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:20:34

[Procedure/Surgery](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                     | 10 Mar 2021 18:07:05 |
| User signature succeeded. | Douglas Denham (b) (4)               | 22 Feb 2021 18:45:07 |
| User entered 'Head CT'    | (b) (4)<br>Antonio Gutierrez (b) (4) | 20 Nov 2020 22:14:29 |



**US3292103**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Indication](#)

| Audit                             | User                                 | Time (GMT)           |
|-----------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)                     | 10 Mar 2021 18:07:05 |
| User signature succeeded.         | Douglas Denham (b) (4)               | 22 Feb 2021 18:45:07 |
| User entered 'Adverse Event (AE)' | (b) (4)<br>Antonio Gutierrez (b) (4) | 20 Nov 2020 22:14:29 |

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:20:34

If indication is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                     | 10 Mar 2021 18:07:05 |
| User signature succeeded. | Douglas Denham (b) (4)               | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>Antonio Gutierrez (b) (4) | 20 Nov 2020 22:14:29 |

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:20:34

Procedure/Surgery date (dd MMM yyyy)

| Audit                      | User                                 | Time (GMT)           |
|----------------------------|--------------------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)                     | 10 Mar 2021 18:07:06 |
| User signature succeeded.  | Douglas Denham (b) (4)               | 22 Feb 2021 18:45:07 |
| User entered '17 Nov 2020' | (b) (4)<br>Antonio Gutierrez (b) (4) | 20 Nov 2020 22:14:49 |

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:20:34

[Procedure/Surgery](#)

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                     | 10 Mar 2021 18:07:06 |
| User signature succeeded. | Douglas Denham (b) (4)               | 22 Feb 2021 18:45:07 |
| User entered 'Head CT'    | (b) (4)<br>Antonio Gutierrez (b) (4) | 20 Nov 2020 22:14:49 |

**US3292103**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Indication](#)

| Audit                             | User                                 | Time (GMT)           |
|-----------------------------------|--------------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)                     | 10 Mar 2021 18:07:06 |
| User signature succeeded.         | Douglas Denham (b) (4)               | 22 Feb 2021 18:45:07 |
| User entered 'Adverse Event (AE)' | (b) (4)<br>Antonio Gutierrez (b) (4) | 20 Nov 2020 22:14:49 |

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:20:34

If indication is Other, specify

| Audit                     | User                                 | Time (GMT)           |
|---------------------------|--------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                     | 10 Mar 2021 18:07:06 |
| User signature succeeded. | Douglas Denham (b) (4)               | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>Antonio Gutierrez (b) (4) | 20 Nov 2020 22:14:49 |

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:20:34

Procedure/Surgery date (dd MMM yyyy)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)     | 08 Apr 2021 16:13:33 |
| DataPoint Verified.  | (b) (4)                    |                      |
|  | (b) (4), (b) (6)           | 25 Mar 2021 20:18:49 |
| User closed query 'Per source, Procedure date is 10Dec2020' (Site from CRA).             | (b) (4), (b) (6)           | 25 Mar 2021 20:18:48 |
| Query 'Per source, Procedure date is 10Dec2020' answered with 'updated' (Site from CRA). | Dawn Killian (b) (4)       | 23 Mar 2021 18:29:57 |
| Signature has been broken.   | (b) (4)                    |                      |
|  | Dawn Killian (b) (4)       | 23 Mar 2021 18:29:51 |
|  | (b) (4)                    |                      |
| User entered '10 Dec 2020' reason for change: Data Entry Error                           | Dawn Killian (b) (4)       | 23 Mar 2021 18:29:51 |
|  | (b) (4)                    |                      |
| User opened query 'Per source, Procedure date is 10Dec2020' (Site from CRA).             | (b) (4), (b) (6)           | 10 Mar 2021 18:07:26 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 22 Feb 2021 18:45:07 |
|  | (b) (4)                    |                      |
| User entered '14 Jan 2021'   | Victoria Hernandez (b) (4) | 18 Jan 2021 19:57:37 |
|  | (b) (4)                    |                      |

**US3292103**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 16:20:34**

[Procedure/Surgery](#)

| Audit                     | User                                  | Time (GMT)           |
|---------------------------|---------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                      | 10 Mar 2021 18:07:30 |
| User signature succeeded. | Douglas Denham (b) (4)                | 22 Feb 2021 18:45:07 |
| User entered 'Head CT'    | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 19:57:37 |



US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:20:34

[Indication](#)

| Audit                             | User                                  | Time (GMT)           |
|-----------------------------------|---------------------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)                      | 10 Mar 2021 18:07:34 |
| User signature succeeded.         | Douglas Denham (b) (4)                | 22 Feb 2021 18:45:07 |
| User entered 'Adverse Event (AE)' | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 19:57:37 |

US3292103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:20:34

If indication is Other, specify

| Audit                     | User                                  | Time (GMT)           |
|---------------------------|---------------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                      | 10 Mar 2021 18:07:37 |
| User signature succeeded. | Douglas Denham (b) (4)                | 22 Feb 2021 18:45:07 |
| User entered empty.       | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 19:57:37 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered<br>'USA-US072-2020-MRNA-1273-P301000013' | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'Yes (Y)'    | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'Yes (Y)'    | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |



**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |

US3292103

Folder: SAE USA-US072-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:20:34

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'Douglas'    | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'Denham'     | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

**Site Address: [Street](#)**

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| User signature succeeded.            | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.                  | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.                 | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered '7940 Floyd Curl Drive' | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Site Address: City](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.       | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'San Antonio' | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered '78229'      | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 17:24:34 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 18 Jan 2021 19:45:53 |
| User entered 'US'         | System                      | 23 Nov 2020 23:38:47 |



**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '2'          | (b) (4)<br>System      | 02 Feb 2021 17:24:45 |
| User entered '1'          | System                 | 23 Nov 2020 23:38:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered<br>'USA-US072-2020-MRNA-1273-P301000013' | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'Yes (Y)'    | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'Yes (Y)'    | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |



US3292103

Folder: SAE USA-US072-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:20:34

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |

US3292103

Folder: SAE USA-US072-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:20:34

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'Douglas'    | System                      | 23 Nov 2020 23:37:47 |

US3292103

Folder: SAE USA-US072-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:20:34

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'Denham'     | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Site Address: Street](#)

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| User signature succeeded.            | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.                  | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.                 | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered '7940 Floyd Curl Drive' | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Site Address: City](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.       | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'San Antonio' | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered '78229'      | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Investigator Country](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| Reviewed for Safety.      | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 02 Feb 2021 17:24:34 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 18 Jan 2021 19:45:53 |
| User entered 'US'         | System                 | 23 Nov 2020 23:38:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '2'          | (b) (4)<br>System      | 02 Feb 2021 17:24:45 |
| User entered '1'          | System                 | 23 Nov 2020 23:38:47 |



**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:20:34**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| User entered '23/Nov/2020 18:38' | System                      | 23 Nov 2020 23:38:47 |

US3292103

Folder: SAE USA-US072-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:20:34

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| Reviewed for Safety.      | (b) (4)                | 02 Feb 2021 17:24:34 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 18 Jan 2021 19:45:53 |
| User entered 'l'          |                        | 23 Nov 2020 23:38:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.                                  | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered<br>'USA-US072-2020-MRNA-1273-P301000013' | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'Yes (Y)'    | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'Yes (Y)'    | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |



**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'No (N)'     | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'Douglas'    | System                      | 23 Nov 2020 23:37:47 |

US3292103

Folder: SAE USA-US072-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 16:20:34

[Investigator's Last Name](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)       | 23 Nov 2020 23:38:40 |
| User entered 'Denham'     | System                 | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Site Address: Street](#)

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| User signature succeeded.            | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.                  | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.                 | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered '7940 Floyd Curl Drive' | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Site Address: City](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.       | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered 'San Antonio' | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 19:45:53 |
| Reviewed for Safety.      | (b) (4), (b) (6)            | 23 Nov 2020 23:38:40 |
| User entered '78229'      | System                      | 23 Nov 2020 23:37:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Feb 2021 18:45:07 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Feb 2021 17:24:34 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 18 Jan 2021 19:45:53 |
| User entered 'US'         | System                      | 23 Nov 2020 23:38:47 |



**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:20:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '2'          | (b) (4)<br>System      | 02 Feb 2021 17:24:45 |
| User entered '1'          | System                 | 23 Nov 2020 23:38:47 |

**US3292103**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000013**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:20:34**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 10 Mar 2021 17:07:51 |
| User signature succeeded.        | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered '02/Feb/2021 17:24' | (b) (4)<br>System      | 02 Feb 2021 17:24:45 |

US3292103

Folder: SAE USA-US072-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:20:34

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)       | 10 Mar 2021 17:07:51 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Feb 2021 18:45:07 |
| User entered 'I'          | (b) (4), (b) (6)       | 02 Feb 2021 17:24:45 |