

US3292324 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:34:27

All time stamps listed in this document are displayed in GMT

US3292324

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 14:15:24

Generated On: 09 Jun 2021 16:34:27

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[Participant ID](#)

US3292324

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

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US3292324

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 27 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) 05 Mar 2021 17:09:00

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| Date of Birth (MMM yyyy)                  | (b) (6) 1954   |
| Age                                       | 66   |
| Age Units                                 | YEARS  |
| Age (Derived)                             | 66   |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>  |
| Ethnicity                                 | Hispanic or Latino <input checked="" type="radio"/><br>Not Hispanic or Latino <input type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |  |
| White                                     | True   |
| Black                                     | False  |
| Asian                                     | False  |
| American Indian or Alaska Native          | False  |
| Native Hawaiian or other Pacific Islander | False  |
| Other                                     | False  |
| If race is Other, specify _____           |  |
| Unknown                                   | False  |
| Not reported                              | False  |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 27 AUG 2020  |
| Month and Year of Informed Consent (derived)    | AUG 2020   |
| Year of Informed Consent (derived)              | 2020   |
| Protocol Version                                | Amendment 1 <input type="radio"/><br>Amendment 2 <input type="radio"/><br>Amendment 3 <input checked="" type="radio"/><br>Amendment 4 <input type="radio"/><br>Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| If No, indicate reason for screen fail          | Withdrew Consent <input type="radio"/><br>Inclusion/Exclusion <input type="radio"/><br>Cohort Full <input type="radio"/><br>Other <input type="radio"/>  |
| If reason for screen fail is Other, specify     |  |
| Was this participant screened previously?       | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If Yes, previous participant number             |  |
| Enrollment Trigger                              | 1  |

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 14:15:49

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 17:09:00

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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) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| Condition   | FENOFIBRATE ALLERGY  |
| Start date (dd MMM yyyy)                                | UN UNK 2010  |
| Start date completely unknown                           | False  |
| Condition ongoing at study entry                        | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ |  |
| Stop date completely unknown                            | False  |
| Start Month and Year (derived)                          | JAN 2010   |
| Start Year (derived)                                    | 2010   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Apr 2021 15:51:45

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| Condition   | LEFT FEMUR<br>RECONSTRUCTION                                     |
| Start date (dd MMM yyyy)                          | UN UNK 2015  |
| 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 2015  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2015   |
| Start Year (derived)                              | 2015   |
| Stop Month and Year (derived)                     | JAN 2015   |
| Stop Year (derived)                               | 2015   |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Apr 2021 15:51:45

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|   |  |
|---|--|
| Condition   | MASTECTOMY - BILATERAL   |
| Start date (dd MMM yyyy)                          | UN UNK 2014  |
| 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 2014  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2014   |
| Start Year (derived)                              | 2014   |
| Stop Month and Year (derived)                     | JAN 2014   |
| Stop Year (derived)                               | 2014   |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Apr 2021 15:51:45

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|   |  |
|---|--|
| Condition   | THYROIDECTOMY  |
| Start date (dd MMM yyyy)                          | UN UNK 2014  |
| 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 2014  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2014   |
| Start Year (derived)                              | 2014   |
| Stop Month and Year (derived)                     | JAN 2014   |
| Stop Year (derived)                               | 2014   |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Apr 2021 15:51:45

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|   |  |
|---|--|
| Condition   | HYSTERECTOMY   |
| Start date (dd MMM yyyy)                          | UN UNK 2005  |
| 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 2005  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2005   |
| Start Year (derived)                              | 2005   |
| Stop Month and Year (derived)                     | JAN 2005   |
| Stop Year (derived)                               | 2005   |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Apr 2021 15:51:45

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|   |  |
|---|--|
| Condition   | CHOLECYSTECTOMY  |
| Start date (dd MMM yyyy)                          | UN UNK 2017  |
| 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 2017  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2017   |
| Start Year (derived)                              | 2017   |
| Stop Month and Year (derived)                     | JAN 2017   |
| Stop Year (derived)                               | 2017   |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Apr 2021 15:51:45

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Apr 2021 15:51:45

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|   |  |
|---|--|
| Condition   | BILATERAL DECREASED<br>VISUAL ACUITY                             |
| Start date (dd MMM yyyy)                          | UN UNK 2010  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2010   |
| Start Year (derived)                              | 2010   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Apr 2021 15:51:45

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|   |  |
|---|--|
| Condition   | CHOLELITHIASIS   |
| Start date (dd MMM yyyy)                          | UN UNK 2017  |
| 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 2017  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2017   |
| Start Year (derived)                              | 2017   |
| Stop Month and Year (derived)                     | JAN 2017   |
| Stop Year (derived)                               | 2017   |

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Apr 2021 15:51:45

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|   |  |
|---|--|
| Condition   | OBESITY  |
| Start date (dd MMM yyyy)                          |  |
| Start date completely unknown                     | True   |
| 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 2008  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    |  |
| Start Year (derived)                              |  |
| Stop Month and Year (derived)                     | JAN 2008   |
| Stop Year (derived)                               | 2008   |

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| Condition   | BILATERAL BREAST DUCTAL<br>CARCINOMA IN SITU                     |
| Start date (dd MMM yyyy)                          | UN UNK 2014  |
| 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 2014  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2014   |
| Start Year (derived)                              | 2014   |
| Stop Month and Year (derived)                     | JAN 2014   |
| Stop Year (derived)                               | 2014   |

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| Condition   | THYROID GLAND PAPILLARY<br>CANCER                                |
| Start date (dd MMM yyyy)                          | UN UNK 2014  |
| 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 2014  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2014   |
| Start Year (derived)                              | 2014   |
| Stop Month and Year (derived)                     | JAN 2014   |
| Stop Year (derived)                               | 2014   |

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| Condition   | UTERINE FIBROIDS   |
| Start date (dd MMM yyyy)                          | UN UNK 2005  |
| 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 2005  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2005   |
| Start Year (derived)                              | 2005   |
| Stop Month and Year (derived)                     | JAN 2005   |
| Stop Year (derived)                               | 2005   |

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| Condition   | OSTEOARTHRITIS BILATERAL<br>KNEES                                |
| Start date (dd MMM yyyy)                          | UN UNK 1973  |
| 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 1973   |
| Start Year (derived)                              | 1973   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| Condition   | LEFT FEMUR FRACTURE  |
| Start date (dd MMM yyyy)                          | UN UNK 2015  |
| 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 2015  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2015   |
| Start Year (derived)                              | 2015   |
| Stop Month and Year (derived)                     | JAN 2015   |
| Stop Year (derived)                               | 2015   |



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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| Condition   | OSTEOPENIA   |
| Start date (dd MMM yyyy)                                | UN UNK 2014  |
| 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 2014   |
| Start Year (derived)                                    | 2014   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|                                     |                                      |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/> |
|                                     | No <input type="radio"/>             |
| Date of assessment (dd MMM yyyy)    | 27 AUG 2020                          |
| Time of assessment (00:00-23:59)    | 08:44 (24 HR)                        |
| Vital Signs Date and Time (derived) | 27 AUG 2020 08:44                    |
| Height (xxx.x)                      | 163.0 cm                             |
| Weight (xxx.x)                      | 93.5 kg                              |
| BMI (xxx.x)                         | 35.19139 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) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 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) 23 Feb 2021 14:15:49

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Date of assessment (dd MMM yyyy) 27 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) UN UNK 2005

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 14:15:50

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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**

---

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 14:15:50

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 27 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) 16 Apr 2021 14:42:31

Generated On: 09 Jun 2021 16:34:27

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 188281

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|        |               |
|--------|---------------|
| 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) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|                                     |  |
|-------------------------------------|--|
| 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)    | 27 AUG 2020  |
| Time of assessment (00:00-23:59)    | 09:25 (24 HR)  |
| Vital Signs Date and Time (derived) | 27 AUG 2020 09:25  |
| Temperature (xxx.x)                 | 036.8 C  |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 065 beats/min  |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 016 breaths/min  |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 131 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 081 mmHg   |
| Diastolic Blood Pressure units      | MMHG   |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| Timepoint                           | Pre-Dose <input type="radio"/><br>Post-Dose <input checked="" type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 27 AUG 2020  |
| Time of assessment (00:00-23:59)    | 11:00 (24 HR)  |
| Vital Signs Date and Time (derived) | 27 AUG 2020 11:00  |
| Temperature (xxx.x)                 | 036.7 C  |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 066 beats/min  |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 012 breaths/min  |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 120 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 076 mmHg   |
| Diastolic Blood Pressure units      | MMHG   |

US3292324

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

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.*

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 10:30 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 10:30

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

US3292324

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 27 AUG 2020                          |
| Collection time (00:00-23:59)      | 09:36 (24 HR)                        |
| Collection date and time (derived) | 27 AUG 2020 09:36                    |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 27 AUG 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 09:47                           | 27 AUG 2020 09:47                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3292324

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**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

27 AUG 2020 11:03

PC Open Date & Time

27 AUG 2020 10:50

PC Close Date & Time

27 AUG 2020 13:20

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 19:29

PC Open Date & Time

27 AUG 2020 14:15

PC Close Date & Time

28 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 18:52

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

30 AUG 2020 07:41

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °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

30 AUG 2020 19:58

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 20:07

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 20:54

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**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

98.2 °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

02 SEP 2020 19:46

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59



US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 11:04

PC Open Date & Time

27 AUG 2020 10:50

PC Close Date & Time

27 AUG 2020 13:20

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**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

27 AUG 2020 19:30

PC Open Date & Time

27 AUG 2020 14:15

PC Close Date & Time

28 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 18:53

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**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

30 AUG 2020 07:41

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**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

30 AUG 2020 19:59

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**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

31 AUG 2020 20:07

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 20:55

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 19:46

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59



US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**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 ☐

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 27 AUG 2020 11:04 |
| PC Open Date & Time  | 27 AUG 2020 10:50 |
| PC Close Date & Time | 27 AUG 2020 13:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**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 ☐

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 27 AUG 2020 19:30 |
| PC Open Date & Time  | 27 AUG 2020 14:15 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 28 AUG 2020 18:54 |
| PC Open Date & Time          | 28 AUG 2020 12:00 |
| PC Close Date & Time         | 29 AUG 2020 11:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 30 AUG 2020 07:42 |
| PC Open Date & Time          | 29 AUG 2020 12:00 |
| PC Close Date & Time         | 30 AUG 2020 11:59 |



US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 30 AUG 2020 19:59 |
| PC Open Date & Time          | 30 AUG 2020 12:00 |
| PC Close Date & Time         | 31 AUG 2020 11:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 31 AUG 2020 20:10 |
| PC Open Date & Time          | 31 AUG 2020 12:00 |
| PC Close Date & Time         | 01 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 01 SEP 2020 20:57 |
| PC Open Date & Time          | 01 SEP 2020 12:00 |
| PC Close Date & Time         | 02 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 SEP 2020 19:47 |
| PC Open Date & Time          | 02 SEP 2020 12:00 |
| PC Close Date & Time         | 03 SEP 2020 11:59 |



US3292324

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292324

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments ATTEMPTS WERE MADE, BUT  
STAFF UNABLE TO CONTACT  
If Contact Not Made, please provide Comments PATIENT

US3292324

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292324

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 24 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                                  |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|                                     |   |
|-------------------------------------|---|
| 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)    | 24 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 09:15 (24 HR)                             |
| Vital Signs Date and Time (derived) | 24 SEP 2020 09:15                         |
| Temperature (xxx.x)                 | 36.9 C                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 67 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 12 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 115 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 64 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |



US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|                                     |   |
|-------------------------------------|---|
| 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)    | 24 SEP 2020                                   |
| Time of assessment (00:00-23:59)    | 10:29 (24 HR)                                 |
| Vital Signs Date and Time (derived) | 24 SEP 2020 10:29                             |
| Temperature (xxx.x)                 | 36.6 C  |
| Route of measurement                | Oral <input checked="" type="checkbox"/>      |
|                                     | Axillary <input type="checkbox"/>             |
|                                     | Other <input type="checkbox"/>                |
| If Other, specify                   |   |
| Pulse (xxx)                         | 68 beats/min                                  |
| Pulse units                         | BPM   |
| Respiratory Rate (xxx)              | 12 breaths/min                                |
| Respiratory Rate units              | BREATHS/MIN                                   |
| Systolic Blood Pressure (xxx)       | 117 mmHg                                      |
| Systolic Blood Pressure units       | MMHG  |
| Diastolic Blood Pressure (xxx)      | 74 mmHg                                       |
| Diastolic Blood Pressure units      | MMHG  |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

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) 24 SEP 2020

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

Treatment Date and Time (derived) 24 SEP 2020 09:59

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

US3292324

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 24 SEP 2020                          |
| Collection time (00:00-23:59)      | 09:22 (24 HR)                        |
| Collection date and time (derived) | 24 SEP 2020 09:22                    |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 24 SEP 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 09:40                           | 24 SEP 2020 09:40                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 10:32

PC Open Date & Time

24 SEP 2020 10:19

PC Close Date & Time

24 SEP 2020 12:49

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐  
No ☒

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 24 SEP 2020 19:49 |
| PC Open Date & Time  | 24 SEP 2020 13:44 |
| PC Close Date & Time | 25 SEP 2020 11:59 |



US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

|  |                                      |
|--|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 99.6 °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        | 25 SEP 2020 18:32 |
| PC Open Date & Time  | 25 SEP 2020 12:00 |
| PC Close Date & Time | 26 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 11:06

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 20:12

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 18:59

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 07:01

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**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

01 OCT 2020 07:02

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**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

24 SEP 2020 10:32

PC Open Date & Time

24 SEP 2020 10:19

PC Close Date & Time

24 SEP 2020 12:49

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**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

24 SEP 2020 19:49

PC Open Date & Time

24 SEP 2020 13:44

PC Close Date & Time

25 SEP 2020 11:59



US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**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

25 SEP 2020 18:32

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**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

27 SEP 2020 11:07

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**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

27 SEP 2020 20:12

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**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

28 SEP 2020 19:00

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**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

30 SEP 2020 07:01

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**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

01 OCT 2020 07:02

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**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 ☐

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 24 SEP 2020 10:32 |
| PC Open Date & Time  | 24 SEP 2020 10:19 |
| PC Close Date & Time | 24 SEP 2020 12:49 |



US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**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 ☐

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 24 SEP 2020 19:49 |
| PC Open Date & Time  | 24 SEP 2020 13:44 |
| PC Close Date & Time | 25 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☒

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 25 SEP 2020 18:34 |
| PC Open Date & Time          | 25 SEP 2020 12:00 |
| PC Close Date & Time         | 26 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 27 SEP 2020 11:07 |
| PC Open Date & Time          | 26 SEP 2020 12:00 |
| PC Close Date & Time         | 27 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 27 SEP 2020 20:13 |
| PC Open Date & Time          | 27 SEP 2020 12:00 |
| PC Close Date & Time         | 28 SEP 2020 11:59 |



US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

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 16:34:27

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 28 SEP 2020 19:00 |
| PC Open Date & Time          | 28 SEP 2020 12:00 |
| PC Close Date & Time         | 29 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 30 SEP 2020 07:02 |
| PC Open Date & Time          | 29 SEP 2020 12:00 |
| PC Close Date & Time         | 30 SEP 2020 11:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 01 OCT 2020 07:02 |
| PC Open Date & Time          | 30 SEP 2020 12:00 |
| PC Close Date & Time         | 01 OCT 2020 11:59 |

US3292324

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292324

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3292324

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292324

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292324

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 22 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                                  |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 22 OCT 2020                           |
| Time of assessment (00:00-23:59)    | 09:12 (24 HR)                         |
| Vital Signs Date and Time (derived) | 22 OCT 2020 09:12                     |
| Temperature (xxx.x)                 | 37.1 C                                |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 75 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 12 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 123 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 75 mmHg                               |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

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.*

US3292324

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

09:22 (24 HR)

Collection date and time (derived)

22 OCT 2020 09:22



US3292324

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:15:50

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| <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   | 27 OCT 2020 07:43:45   |
| Patient Cloud Open Date & Time  | 27 OCT 2020 00:01  |
| Patient Cloud Close Date & Time   | 31 OCT 2020 23:59  |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| TIMEPOINT   | DAY 71   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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   | 04 NOV 2020 19:53:42   |
| Patient Cloud Open Date & Time  | 03 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 07 NOV 2020 23:59  |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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 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   | 11 NOV 2020 12:04:48   |
| Patient Cloud Open Date & Time  | 10 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 14 NOV 2020 23:59  |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| TIMEPOINT   | DAY 89   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><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   | 21 NOV 2020 03:28:42   |
| Patient Cloud Open Date & Time  | 21 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 25 NOV 2020 23:59  |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| TIMEPOINT   | DAY 96   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 28 NOV 2020 00:05:25   |
| Patient Cloud Open Date & Time  | 28 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 02 DEC 2020 23:59  |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 08:14:19

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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   | 12 DEC 2020 03:03:38   |
| Patient Cloud Open Date & Time  | 12 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 16 DEC 2020 23:59  |



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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

19 DEC 2020 07:19:34

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 124  |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 26 DEC 2020 04:56:59   |
| Patient Cloud Open Date & Time  | 26 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 30 DEC 2020 23:59  |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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

02 JAN 2021 10:57:20

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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

09 JAN 2021 00:40:51

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 145  |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 16 JAN 2021 05:44:39   |
| Patient Cloud Open Date & Time  | 16 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 20 JAN 2021 23:59  |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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

23 JAN 2021 00:01:47

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | 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 <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 JAN 2021 07:14:12   |
| Patient Cloud Open Date & Time  | 30 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 03 FEB 2021 23:59  |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| <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   | 06 FEB 2021 04:43:49   |
| Patient Cloud Open Date & Time  | 06 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 10 FEB 2021 23:59  |



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 09:38:25

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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 <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 FEB 2021 01:34:42   |
| Patient Cloud Open Date & Time  | 20 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 24 FEB 2021 23:59  |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 23:30:10

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| TIMEPOINT   | DAY 194  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 06 MAR 2021 07:15:36   |
| Patient Cloud Open Date & Time  | 06 MAR 2021 00:01  |
| Patient Cloud Close Date & Time   | 10 MAR 2021 23:59  |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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

13 MAR 2021 06:02:45

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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

23 MAR 2021 03:52:17

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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

27 MAR 2021 23:17:40

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | 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 <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   | 03 APR 2021 00:24:54   |
| Patient Cloud Open Date & Time  | 03 APR 2021 00:01  |
| Patient Cloud Close Date & Time   | 07 APR 2021 23:59  |



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 229  |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 11 APR 2021 19:02:35   |
| Patient Cloud Open Date & Time  | 10 APR 2021 00:01  |
| Patient Cloud Close Date & Time   | 14 APR 2021 23:59  |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| <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   | 17 APR 2021 04:43:40   |
| Patient Cloud Open Date & Time  | 17 APR 2021 00:01  |
| Patient Cloud Close Date & Time   | 21 APR 2021 23:59  |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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

24 APR 2021 07:10:55

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 250  |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 01 MAY 2021 07:48:09   |
| Patient Cloud Open Date & Time  | 01 MAY 2021 00:01  |
| Patient Cloud Close Date & Time   | 05 MAY 2021 23:59  |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐ 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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 12 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 16 JUN 2021 23:59 |



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐ 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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 26 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 30 JUN 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 10 JUL 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 JUL 2021 23:59 |



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| TIMEPOINT   | DAY 327   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 17 JUL 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 21 JUL 2021 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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31 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Close Date & Time](#)

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18 AUG 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Close Date & Time](#)

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08 SEP 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Close Date & Time](#)

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13 OCT 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| TIMEPOINT   | DAY 488   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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|  |                   |
|--|-------------------|
| <a href="#">Patient Cloud Open Date &amp; Time</a> | 25 DEC 2021 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 DEC 2021 23:59 |
|---|-------------------|

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Close Date & Time](#)

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12 JAN 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 22 JAN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 JAN 2022 23:59 |



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Open Date & Time](#)

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05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 12 FEB 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 16 FEB 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| TIMEPOINT   | DAY 544   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 02 APR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 06 APR 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 16 APR 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 20 APR 2022 23:59 |



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐ 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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐ 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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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22 JUN 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 JUN 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 16 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 20 JUL 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐ 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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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13 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 AUG 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 27 AUG 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 31 AUG 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Close Date & Time](#)

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21 SEP 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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[Patient Cloud Close Date & Time](#)

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28 SEP 2022 23:59

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 01 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 05 OCT 2022 23:59 |



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**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 ☐

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 OCT 2022 23:59 |
|---|-------------------|

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US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 22 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 OCT 2022 23:59 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

| 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"/>   |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2022 23:59

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US3292324

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:34:27

| 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  |  | 27 FEB 2021 23:30:32      |

US3292324

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292324

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292324

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292324

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:42:47

Generated On: 09 Jun 2021 16:34:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3292324

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:42:47

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292324

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:42:31

Generated On: 09 Jun 2021 16:34:27

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 23 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                                  |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:42:31

Generated On: 09 Jun 2021 16:34:27

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) \_\_\_\_\_

US3292324

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:42:31

Generated On: 09 Jun 2021 16:34:27

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.*

US3292324

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:42:31

Generated On: 09 Jun 2021 16:34:27

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

|                               |             |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 23 MAR 2021 |
|-------------------------------|-------------|

|                               |               |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 09:45 (24 HR) |
|-------------------------------|---------------|

|                                    |                   |
|------------------------------------|-------------------|
| Collection date and time (derived) | 23 MAR 2021 09:45 |
|------------------------------------|-------------------|

US3292324

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:42:31

Generated On: 09 Jun 2021 16:34:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3292324**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:34:27**

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*

**US3292324**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:34:27**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3292324

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:34:27

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

**US3292324**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 16:34:27**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3292324

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 14 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                           |

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:42:31

Generated On: 09 Jun 2021 16:34:27

Date of updated informed consent (dd MMM yyyy) 14 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) 14 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 \_\_\_\_\_

US3292324

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 14 JAN 2021                          |
| Collection time (00:00-23:59)      | 10:15 (24 HR)                        |
| Collection date and time (derived) | 14 JAN 2021 10:15                    |

US3292324

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 14 JAN 2021                          |
| Collection time (00:00 - 23:59)    | 10:20                                |
| Collection Date and Time (derived) | 14 JAN 2021 10:20                    |

US3292324

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 14:15:24

Generated On: 09 Jun 2021 16:34:27

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)



US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

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

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

|  |  |
|--|--|
| AEID   | USA-US072-2020-MRNA-1273-P30<br>1000008  |
| Adverse event  | R BROKEN FEMUR   |
| 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)                                       | 3 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)                         | 22 DEC 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 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)                          | 03 NOV 2020  |
| Hospital Discharge Date (dd MMM yyyy)                          | 19 NOV 2020  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>  |

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

|  |   |
|--|---|
| Number of Days in ICU  |   |
| Persistent or significant disability or incapacity                           | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product                                    | None <input 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   | False   |
| 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  |   |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

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SUBJECT CALLED TO INFORM  
US SHE IS CURRENTLY  
ADMITTED AT METROPOLITAN  
METHODIST FOR A BROKEN  
FEMUR. SHE STATES SHE  
BROKE HER FEMUR  
YESTERDAY(03-NOV-2020)  
DURING A FALL PICKING UP  
HER GROCERIES. SHE WENT TO  
THE ER (AT HOSPITAL STATED  
ABOVE) AND WAS TAKEN TO  
THE OR FOR SURGERY FOR  
REPAIR. SHE IS CURRENTLY  
STAYING FOR OBSERVATION  
AND IS EXPECTED TO STAY  
FOR ABOUT 3-4 DAYS.  
RECORDS WILL BE  
REQUESTED.

---

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

---

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | SHINGLES   |
| 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 SEP 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)                         | 24 SEP 2020  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input 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 (3)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

|  |  |
|--|--|
| 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)                                       | 03 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)                         | 03 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 (4)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

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



US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Data signed:** (b) (4) 23 Feb 2021 14:15:49

**Generated On: 09 Jun 2021 16:34:27**

---

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) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

Name of Medication CENTRUM SILVER

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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 2010              |                                  |
| 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"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

Name of Medication B12

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

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

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

Name of Medication BIOTIN

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           | 20 AUG 2020              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

Name of Medication SYNTHROID

Prophylaxis Yes ☐  
No ☒

Indication THYROID CANCER

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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 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 (5)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication FEVER/PAIN (EDIARY)

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | 25 SEP 2020              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 25 SEP 2020                         |
| Was this medication taken for solicited event?     | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input type="checkbox"/>            |
| Separate Dosage Number (derived)                   | 1                        |                                     |
| Interval Dosage Unit Number (derived)              | 1                        |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

Name of Medication SULFAMETHOXAZOLE

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT INFECTION

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 (6)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           |                          | 16 SEP 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 26 SEP 2020 |                          |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   |                          | 2                                   |
| Interval Dosage Unit Number (derived)              |                          | 1                                   |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

Name of Medication ACYCLOVIR

Prophylaxis Yes ☐  
No ☒

Indication SHINGLES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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 SEP 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) 24 SEP 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"/> |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

Name of Medication BONIVA

Prophylaxis Yes ☐  
No ☒

Indication OSTEOPENIA

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:51:44

Generated On: 09 Jun 2021 16:34:27

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           | 19 MAR 2021              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input checked="" type="radio"/> |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

US3292324

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3292324

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Feb 2021 14:15:49

Generated On: 09 Jun 2021 16:34:27

| Procedure/Surgery date ( <i>dd MMM</i><br><i>yyyy</i> ) | Procedure/Surgery  | Indication    | If indication is Other, specify |
|---|--------------------|---------------|---------------------------------|
| 4 NOV 2020  | RIGHT FEMUR REPAIR | Adverse Event |                                 |

US3292324

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:34:27

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

US3292324

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:34:27

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 ☐

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|  |  |
|--|--|
| SAEID  | USA-US072-2020-MRNA-1273-P301000008                              |
| 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)                             | 6  |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| SAEID   | USA-US072-2020-MRNA-1273-P301000008                              |
| 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)  | 6  |
| Date of submission (Pre-filled from custom function)  | 04/NOV/2020 18:49  |
| 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   |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| SAEID   | USA-US072-2020-MRNA-1273-P301000008                              |
| 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)  | 6  |
| Date of submission (Pre-filled from custom function)  | 11/DEC/2020 05:51  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |



US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| SAEID   | USA-US072-2020-MRNA-1273-P301000008                              |
| 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)  | 6  |
| Date of submission (Pre-filled from custom function)  | 21/JAN/2021 15:29  |
| 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   |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| SAEID   | USA-US072-2020-MRNA-1273-P301000008                              |
| 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)  | 6  |
| Date of submission (Pre-filled from custom function)  | 25/MAR/2021 08:40  |
| 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   |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| SAEID   | USA-US072-2020-MRNA-1273-P301000008                              |
| 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)  | 6  |
| Date of submission (Pre-filled from custom function)  | 21/APR/2021 16:52  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 22 Apr 2021 15:51:45

Generated On: 09 Jun 2021 16:34:27

|   |  |
|---|--|
| SAEID   | USA-US072-2020-MRNA-1273-P301000008                              |
| 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)  | 6  |
| Date of submission (Pre-filled from custom function)  | 21/APR/2021 17:13  |
| 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

US3292324 (Prod: Clinical Trials of Texas, Inc)

**US3292324**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:34:27**

[Participant ID](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)           | 23 Feb 2021 14:15:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 19 Jan 2021 21:23:28 |
| User entered 'US3292324'  | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 27 Aug 2020 14:14:42 |

**US3292324**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:34:27**

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:30:35 |
| User entered 'Yes (Y)'    |                        | 28 Aug 2020 12:38:44                  |

US3292324

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 28 Apr 2021 18:23:09 |
| User signature succeeded.  | Douglas Denham (b) (4)           | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 08 Feb 2021 19:30:35 |
| User entered '27 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 27 Aug 2020 14:14:43 |



US3292324

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[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 18:23:09 |
| User signature succeeded.      | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.            | (b) (4)                | 08 Feb 2021 19:30:35 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6)       | 28 Aug 2020 12:38:44 |

**US3292324**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:34:27**

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'SCRN' | System           | 28 Aug 2020 12:38:44 |

US3292324

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:34:27

Date of Birth (MMM yyyy)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 28 Apr 2021 18:23:09 |
| User signature succeeded.                                  | Douglas Denham (b) (4)           | 05 Mar 2021 17:09:00 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)      | 03 Mar 2021 21:48:58 |
| Query 'Please Provide Source' canceled (Site from CRA).    |                                  | 03 Mar 2021 21:48:47 |
| User opened query 'Please Provide Source' (Site from CRA). |                                  | 08 Feb 2021 19:30:11 |
| User entered (b) (6) 1954'                                 | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 27 Aug 2020 14:14:44 |

US3292324

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:34:27

[Age](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:09:00 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 03 Mar 2021 21:48:58 |
| User entered '66'         |                        | 28 Aug 2020 12:39:06 |

**US3292324**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:34:27**

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'YEARS' | System           | 28 Aug 2020 12:39:06 |

US3292324

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:34:27

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '66' | System           | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:34:27

[Sex](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:09:00 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 03 Mar 2021 21:48:58 |
| User entered 'Female (F)' |                        | 28 Aug 2020 12:39:06 |

US3292324

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:34:27

[Ethnicity](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.                              | Douglas Denham (b) (4) | 05 Mar 2021 17:09:00 |
| DataPoint Verified.                                    | (b) (4), (b) (6)       | 03 Mar 2021 21:48:58 |
| User entered 'Hispanic or Latino (HISPANIC OR LATINO)' | (b) (4), (b) (6)       | 28 Aug 2020 12:39:06 |



**US3292324**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:34:27**

[White](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4)      | 05 Mar 2021 17:09:00 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 03 Mar 2021 21:48:58 |
| User entered 'l'          |                             | 28 Aug 2020 12:39:06 |

US3292324

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:34:27

[Black](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:09:00 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 03 Mar 2021 21:48:58 |
| User entered '0'          |                        | 28 Aug 2020 12:39:06 |

**US3292324**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:34:27**

[Asian](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:09:00 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 03 Mar 2021 21:48:58 |
| User entered '0'          |                        | 28 Aug 2020 12:39:06 |

US3292324

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:34:27

[American Indian or Alaska Native](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:09:00 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 03 Mar 2021 21:48:58 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:39:06 |

**US3292324**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:34:27**

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4)      | 05 Mar 2021 17:09:00 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 03 Mar 2021 21:48:58 |
| User entered '0'          |                             | 28 Aug 2020 12:39:06 |

**US3292324**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:34:27**

[Other](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:09:00 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 03 Mar 2021 21:48:58 |
| User entered '0'          |                        | 28 Aug 2020 12:39:06 |

US3292324

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:34:27

[If race is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4)      | 05 Mar 2021 17:09:00 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 03 Mar 2021 21:48:58 |
| User entered empty.       |                             | 28 Aug 2020 12:39:06 |

US3292324

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:34:27

Unknown

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:09:00 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 03 Mar 2021 21:48:58 |
| User entered '0'          |                        | 28 Aug 2020 12:39:06 |



**US3292324**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:34:27**

[Not reported](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 05 Mar 2021 17:09:00 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 03 Mar 2021 21:48:58 |
| User entered '0'          |                        | 28 Aug 2020 12:39:06 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:34:27

Date of Informed Consent (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:30:27 |
| User entered '27 Aug 2020' | Nathan Cortez (b) (4)  | 27 Aug 2020 15:42:45 |

**US3292324**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Aug 2020' | System           | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2020' | System           | 27 Aug 2020 15:42:45 |

**US3292324**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:34:27**

[Protocol Version](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.      | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.            | (b) (4), (b) (6)       | 08 Feb 2021 19:30:27 |
| User entered 'Amendment 3 (3)' | Nathan Cortez (b) (4)  | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:30:27 |
| User entered 'Yes (Y)'    | Nathan Cortez (b) (4)  | 27 Aug 2020 15:42:45 |

**US3292324**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:34:27**

[If No, indicate reason for screen fail](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:30:27 |
| User entered empty.       | Nathan Cortez (b) (4)  | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:34:27

If reason for screen fail is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:30:27 |
| User entered empty.       | Nathan Cortez (b) (4)  | 27 Aug 2020 15:42:45 |



US3292324

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:34:27

[Was this participant screened previously?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:30:27 |
| User entered 'No (N)'     | Nathan Cortez (b) (4)  | 27 Aug 2020 15:42:45 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:34:27

[If Yes, previous participant number](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4)           | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 08 Feb 2021 19:30:27 |
| User entered empty.       | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 27 Aug 2020 14:14:43 |

US3292324

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:34:27

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'l'  | System           | 27 Aug 2020 15:42:56 |

US3292324

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:30:51 |
| User entered 'Yes (Y)'    | Nathan Cortez (b) (4)  | 27 Aug 2020 15:42:56 |

US3292324

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:34:27

[Were any significant conditions reported?](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.                                  | Douglas Denham (b) (4) | 05 Mar 2021 17:09:00 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 03 Mar 2021 21:49:57 |
| Query 'Please Provide Source' canceled (Site from CRA).    |                        | 03 Mar 2021 21:49:55 |
| User opened query 'Please Provide Source' (Site from CRA). |                        | 08 Feb 2021 19:31:09 |
| User entered 'Yes (Y)'                                     |                        | 28 Aug 2020 12:39:11 |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 18:23:09 |
| DataPoint Verified.  | (b) (4)                         | 03 Mar 2021 21:50:51 |
| User signature succeeded.  | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 31 Aug 2020 15:26:36 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)            | 31 Aug 2020 15:26:36 |
| Data point term sent to Coder  | System                          | 28 Aug 2020 12:48:35 |
| User entered 'fenofibrate allergy'   | (b) (4), (b) (6)                | 28 Aug 2020 12:47:43 |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        | (b) (4)                | 03 Mar 2021 21:50:51 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2010' | (b) (4), (b) (6)       | 28 Aug 2020 12:47:43 |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:50:51 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:47:43 |



US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:50:51 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:47:43 |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:50:51 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 12:47:43 |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:50:51 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:47:43 |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2010' | System           | 28 Aug 2020 12:47:43 |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2010' | System           | 28 Aug 2020 12:47:43 |

**US3292324**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 28 Aug 2020 12:47:43 |

US3292324

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 28 Aug 2020 12:47:43 |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 28 Apr 2021 18:23:09 |
| DataPoint Verified.   |                                 | 03 Mar 2021 21:51:00 |
| User signature succeeded.   | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Surgical and medical procedures, HLG: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\23.0. | (b) (4)<br>Coder Import (b) (4) | 28 Aug 2020 12:49:49 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)            | 28 Aug 2020 12:49:49 |
| Data point term sent to Coder   | System                          | 28 Aug 2020 12:48:37 |
| User entered 'total left knee replacement'  | (b) (4), (b) (6)                | 28 Aug 2020 12:48:15 |



US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:51:00 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2000' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:48:15 |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:51:00 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:48:15 |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:51:00 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:48:15 |

**US3292324**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:34:27**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        | (b) (4), (b) (6)            | 03 Mar 2021 21:51:00 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2000' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:48:15 |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:51:00 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:48:15 |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2000' | System           | 28 Aug 2020 12:48:15 |

US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2000' | System           | 28 Aug 2020 12:48:15 |

**US3292324**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2000' | System           | 28 Aug 2020 12:48:15 |



US3292324

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2000' | System           | 28 Aug 2020 12:48:15 |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.   | (b) (4)                | 03 Mar 2021 21:51:06 |
| User signature succeeded.   | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).             | (b) (4), (b) (6)       | 15 Oct 2020 21:52:12 |
| Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4)   | 24 Sep 2020 01:03:56 |
| User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).             | (b) (4), (b) (6)       | 09 Sep 2020 19:19:43 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Bone operation, LLT: Bone operation - version MedDRA\23.0.              | Coder Import (b) (4)   | 29 Aug 2020 07:56:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4)   | 29 Aug 2020 07:56:37 |
| Data point term sent to Coder   | System                 | 28 Aug 2020 12:49:40 |
| User entered 'left femur reconstruction'  | (b) (4), (b) (6)       | 28 Aug 2020 12:48:40 |

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:51:06 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2015' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:48:40 |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:51:06 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:48:40 |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:51:06 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:48:40 |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:51:06 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2015' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:48:40 |

**US3292324**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Stop date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                  | 03 Mar 2021 21:51:06 |
| User signature succeeded. | Douglas Denham (b) (4)<br>(b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)                  | 28 Aug 2020 12:48:40 |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2015' | System           | 28 Aug 2020 12:48:40 |



US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2015' | System           | 28 Aug 2020 12:48:40 |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2015' | System           | 28 Aug 2020 12:48:40 |

US3292324

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2015' | System           | 28 Aug 2020 12:48:40 |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:34:27

Condition

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.   | (b) (4)                | 03 Mar 2021 21:51:17 |
| User signature succeeded.   | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Surgical and medical procedures, HLT: Breast therapeutic procedures, HLT: Mastectomies, PT: Mastectomy, LLT: Mastectomy bilateral - version MedDRA\\23.0. | Coder Import (b) (4)   | 29 Aug 2020 07:45:31 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)   | 29 Aug 2020 07:45:31 |
| Data point term sent to Coder   | System                 | 28 Aug 2020 12:49:40 |
| User entered 'mastectomy - bilateral'   | (b) (4), (b) (6)       | 28 Aug 2020 12:49:08 |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:51:17 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2014' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:49:08 |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:51:17 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:49:08 |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:51:17 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 28 Aug 2020 12:49:08 |

**US3292324**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:34:27**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        | (b) (4), (b) (6)                  | 03 Mar 2021 21:51:17 |
| User signature succeeded.  | Douglas Denham (b) (4)<br>(b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2014' | (b) (4), (b) (6)                  | 28 Aug 2020 12:49:08 |



US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:51:17 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:49:08 |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2014' | System           | 28 Aug 2020 12:49:08 |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2014' | System           | 28 Aug 2020 12:49:08 |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2014' | System           | 28 Aug 2020 12:49:08 |

US3292324

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2014' | System           | 28 Aug 2020 12:49:08 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 28 Apr 2021 18:23:09 |
| DataPoint Verified.   | (b) (4)                         | 03 Mar 2021 21:51:31 |
| User signature succeeded.   | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 28 Aug 2020 12:50:36 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)            | 28 Aug 2020 12:50:36 |
| Data point term sent to Coder   | System                          | 28 Aug 2020 12:49:41 |
| User entered 'thyroidectomy'  | (b) (4), (b) (6)                | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:51:31 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2014' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:51:31 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:49:31 |



US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4)                     | 03 Mar 2021 21:51:31 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        | (b) (4)                | 03 Mar 2021 21:51:31 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2014' | (b) (4), (b) (6)       | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:51:31 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2014' | System           | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2014' | System           | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2014' | System           | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2014' | System           | 28 Aug 2020 12:49:31 |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 18:23:09 |
| DataPoint Verified.  | (b) (4)                         | 03 Mar 2021 21:52:26 |
| User signature succeeded.  | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 28 Aug 2020 12:51:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)            | 28 Aug 2020 12:51:41 |
| Data point term sent to Coder  | System                          | 28 Aug 2020 12:50:42 |
| User entered 'hysterectomy'  | (b) (4), (b) (6)                | 28 Aug 2020 12:49:45 |



US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:52:26 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2005' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:49:45 |

**US3292324**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:34:27**

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                  | 03 Mar 2021 21:52:26 |
| User signature succeeded. | Douglas Denham (b) (4)<br>(b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)                  | 28 Aug 2020 12:49:45 |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4)                     | 03 Mar 2021 21:52:26 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:49:45 |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        | (b) (4)                | 03 Mar 2021 21:52:26 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2005' | (b) (4), (b) (6)       | 28 Aug 2020 12:49:45 |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                  | 03 Mar 2021 21:52:26 |
| User signature succeeded. | Douglas Denham (b) (4)<br>(b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)                  | 28 Aug 2020 12:49:45 |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2005' | System           | 28 Aug 2020 12:49:45 |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2005' | System           | 28 Aug 2020 12:49:45 |

US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2005' | System           | 28 Aug 2020 12:49:45 |



US3292324

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2005' | System           | 28 Aug 2020 12:49:45 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 03 Mar 2021 21:52:48 |
| User signature succeeded.   | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Surgical and medical procedures, HLG: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\23.0. | Coder Import (b) (4)   | 28 Aug 2020 12:51:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)   | 28 Aug 2020 12:51:41 |
| Data point term sent to Coder   | System                 | 28 Aug 2020 12:50:43 |
| User entered 'cholecystectomy'  | (b) (4), (b) (6)       | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:52:48 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2017' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:52:48 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:52:48 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:52:48 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2017' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:52:48 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2017' | System           | 28 Aug 2020 12:50:06 |



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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2017' | System           | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2017' | System           | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2017' | System           | 28 Aug 2020 12:50:06 |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 28 Apr 2021 18:23:09 |
| DataPoint Verified.   |                                 | 03 Mar 2021 21:52:57 |
| User signature succeeded.   | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Surgical and medical procedures, HLT: Gastric therapeutic procedures, HLT: Gastric therapeutic procedures, PT: Gastric bypass, LLT: Gastric bypass - version MedDRA\23.0. | (b) (4)<br>Coder Import (b) (4) | 28 Aug 2020 12:51:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)            | 28 Aug 2020 12:51:41 |
| Data point term sent to Coder   | System                          | 28 Aug 2020 12:50:43 |
| User entered 'gastric bypass surgery'   | (b) (4), (b) (6)                | 28 Aug 2020 12:50:27 |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:52:57 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2008' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:50:27 |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4)                | 03 Mar 2021 21:52:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:50:27 |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4)                | 03 Mar 2021 21:52:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 28 Aug 2020 12:50:27 |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 03 Mar 2021 21:52:57 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2008' | (b) (4), (b) (6)       | 28 Aug 2020 12:50:27 |



US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4)                | 03 Mar 2021 21:52:57 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:50:27 |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2008' | System           | 28 Aug 2020 12:50:27 |

**US3292324**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2008' | System           | 28 Aug 2020 12:50:27 |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2008' | System           | 28 Aug 2020 12:50:27 |

US3292324

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2008' | System           | 28 Aug 2020 12:50:27 |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:34:27

Condition

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 28 Apr 2021 18:23:09 |
| DataPoint Verified.   | (b) (4)                         | 03 Mar 2021 21:53:17 |
| User signature succeeded.   | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) of DECREASED VISUAL ACUITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4)<br>(b) (4), (b) (6)     | 08 Oct 2020 15:10:10 |
| ' (Site from DM).   |                                 |                      |
| 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)<br>(b) (4) | 24 Sep 2020 01:04:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)            | 24 Sep 2020 01:04:40 |
| Data point term sent to Coder   | System                          | 24 Sep 2020 01:04:26 |
| Query 'Per DM CLR: Please specify the location (bilateral, left, right) of DECREASED VISUAL ACUITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.             | Dawn Killian (b) (4)<br>(b) (4) | 24 Sep 2020 01:04:18 |
| ' answered with 'updated' (Site from DM).   |                                 |                      |
| Coding entries removed.   | Dawn Killian (b) (4)<br>(b) (4) | 24 Sep 2020 01:04:11 |
| User entered 'bilateral DECREASED VISUAL ACUITY' reason for change: Data Entry Error  | Dawn Killian (b) (4)<br>(b) (4) | 24 Sep 2020 01:04:11 |
| User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) of DECREASED VISUAL ACUITY. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. | (b) (4), (b) (6)                | 09 Sep 2020 19:20:36 |
| ' (Site from DM).   |                                 |                      |

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Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:34:27

[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) | 28 Aug 2020 12:51:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4) | 28 Aug 2020 12:51:41 |
| Data point term sent to Coder  | System               | 28 Aug 2020 12:50:43 |
| User entered 'decreased visual acuity'   | (b) (4), (b) (6)     | 28 Aug 2020 12:50:40 |

**US3292324**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 03 Mar 2021 21:53:17 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2010' | (b) (4), (b) (6)       | 28 Aug 2020 12:50:40 |



US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:53:17 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:50:40 |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:53:17 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:50:40 |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:53:17 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 12:50:40 |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:53:17 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:50:40 |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2010' | System           | 28 Aug 2020 12:50:40 |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2010' | System           | 28 Aug 2020 12:50:40 |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 28 Aug 2020 12:50:40 |

US3292324

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 28 Aug 2020 12:50:40 |



US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 28 Apr 2021 18:23:09 |
| DataPoint Verified.   |                                 | 03 Mar 2021 21:53:25 |
| User signature succeeded.   | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Cholelithiasis - version MedDRA\23.0. | (b) (4)<br>Coder Import (b) (4) | 28 Aug 2020 12:54:37 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)            | 28 Aug 2020 12:54:37 |
| Data point term sent to Coder   | System                          | 28 Aug 2020 12:53:47 |
| User entered 'cholelithiasis'   | (b) (4), (b) (6)                | 28 Aug 2020 12:53:37 |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:53:25 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2017' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:53:37 |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:53:25 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:53:37 |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:53:25 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:53:37 |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                        | 03 Mar 2021 21:53:25 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2017' | (b) (4), (b) (6)       | 28 Aug 2020 12:53:37 |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:53:25 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:53:37 |

**US3292324**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2017' | System           | 28 Aug 2020 12:53:37 |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2017' | System           | 28 Aug 2020 12:53:37 |



US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2017' | System           | 28 Aug 2020 12:53:37 |

US3292324

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2017' | System           | 28 Aug 2020 12:53:37 |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 18:23:09 |
| DataPoint Verified.  | (b) (4)                         | 03 Mar 2021 21:53:37 |
| User signature succeeded.  | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\23.0. | (b) (4)<br>Coder Import (b) (4) | 28 Aug 2020 12:56:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)            | 28 Aug 2020 12:56:43 |
| Data point term sent to Coder  | System                          | 28 Aug 2020 12:55:50 |
| User entered 'obesity'   | (b) (4), (b) (6)                | 28 Aug 2020 12:55:03 |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:53:37 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 12:55:03 |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:53:37 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'l'          | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:55:03 |

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:53:37 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:55:03 |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 03 Mar 2021 21:53:37 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2008' | (b) (4), (b) (6)       | 28 Aug 2020 12:55:03 |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:53:37 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:55:03 |



US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 28 Aug 2020 12:55:03 |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 28 Aug 2020 12:55:03 |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2008' | System           | 28 Aug 2020 12:55:03 |

US3292324

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2008' | System           | 28 Aug 2020 12:55:03 |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:34:27

Condition

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.  | (b) (4)                | 03 Mar 2021 21:53:44 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| 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. | (b) (4), (b) (6)       | 15 Oct 2020 21:52:53 |
| ' (Site from DM).  |                        |                      |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.       | Coder Import (b) (4)   | 24 Sep 2020 01:06:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)   | 24 Sep 2020 01:06:42 |
| 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.             | Dawn Killian (b) (4)   | 24 Sep 2020 01:05:29 |
| ' answered with 'no meds per patient' (Site from DM).  | (b) (4)                |                      |
| Data point term sent to Coder  | System                 | 24 Sep 2020 01:05:27 |
| Coding entries removed.  | Dawn Killian (b) (4)   | 24 Sep 2020 01:05:16 |
| User entered 'Type II Diabetes' reason for change: Data Entry Error  | Dawn Killian (b) (4)   | 24 Sep 2020 01:05:16 |
| 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. | (b) (4), (b) (6)       | 09 Sep 2020 19:21:48 |
| ' (Site from DM).  |                        |                      |

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0. | Coder Import (b) (4) | 28 Aug 2020 15:19:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4) | 28 Aug 2020 15:19:46 |
| Data point term sent to Coder   | System               | 28 Aug 2020 12:56:50 |
| User entered 'DMII'   | (b) (4), (b) (6)     | 28 Aug 2020 12:55:53 |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:53:44 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 1999' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:55:53 |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:53:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:55:53 |



US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:53:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:55:53 |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4)                | 03 Mar 2021 21:53:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 12:55:53 |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:53:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:55:53 |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 1999' | System           | 28 Aug 2020 12:55:53 |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '1999' | System           | 28 Aug 2020 12:55:53 |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 28 Aug 2020 12:55:53 |

US3292324

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 28 Aug 2020 12:55:53 |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:34:27

Condition

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 03 Mar 2021 21:54:12 |
| User signature succeeded.   | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Intraductal proliferative breast lesion, LLT: Ductal carcinoma in situ - version MedDRA\\23.0. | Coder Import (b) (4)   | 30 Aug 2020 21:03:37 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)   | 30 Aug 2020 21:03:37 |
| Data point term sent to Coder   | System                 | 28 Aug 2020 12:56:53 |
| User entered 'bilateral breast ductal carcinoma in situ'  | (b) (4), (b) (6)       | 28 Aug 2020 12:56:33 |



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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:54:12 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2014' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:56:33 |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:54:12 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:56:33 |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:54:12 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:56:33 |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:54:12 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2014' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:56:33 |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:54:12 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:56:33 |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2014' | System           | 28 Aug 2020 12:56:33 |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2014' | System           | 28 Aug 2020 12:56:33 |

US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2014' | System           | 28 Aug 2020 12:56:33 |



US3292324

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2014' | System           | 28 Aug 2020 12:56:33 |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:34:27

Condition

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 03 Mar 2021 21:55:01 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Papillary thyroid cancer, LLT: Papillary thyroid cancer - version MedDRA\23.0. | Coder Import (b) (4)   | 29 Aug 2020 06:21:32 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.   | Coder Import (b) (4)   | 29 Aug 2020 06:21:32 |
| Data point term sent to Coder  | System                 | 28 Aug 2020 13:00:00 |
| User entered 'thyroid gland papillary cancer'  | (b) (4), (b) (6)       | 28 Aug 2020 12:59:28 |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:34:27

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

| Audit   | User                   | Time (GMT)                            |
|---|------------------------|---------------------------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09                  |
| DataPoint Verified.   | (b) (4)                | 03 Mar 2021 21:55:01                  |
| User signature succeeded.   | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| User entered 'UN UNK 2014' reason for change:<br>Data Entry Error | (b) (4)                | (b) (4), (b) (6) 28 Aug 2020 12:59:42 |
| User entered 'un UNK 1973'  | (b) (4)                | 28 Aug 2020 12:59:28                  |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 03 Mar 2021 21:55:01 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 12:59:28 |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:55:01 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:59:28 |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:34:27

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

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.   | (b) (4)                     | 03 Mar 2021 21:55:01 |
| User signature succeeded.   | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'UN UNK 2014' reason for change:<br>Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:59:42 |
| User entered 'un UNK 1973'  | (b) (4)                     | 28 Aug 2020 12:59:28 |

US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:55:01 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 12:59:28 |

**US3292324**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2014' | System           | 28 Aug 2020 12:59:42 |
| User entered 'Jan 1973' | System           | 28 Aug 2020 12:59:28 |



US3292324

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2014' | System           | 28 Aug 2020 12:59:42 |
| User entered '1973' | System           | 28 Aug 2020 12:59:28 |

**US3292324**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2014' | System           | 28 Aug 2020 12:59:42 |
| User entered 'Jan 1973' | System           | 28 Aug 2020 12:59:28 |

**US3292324**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2014' | System           | 28 Aug 2020 12:59:42 |
| User entered '1973' | System           | 28 Aug 2020 12:59:28 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 18:23:09 |
| DataPoint Verified.  | (b) (4)                         | 03 Mar 2021 21:55:36 |
| User signature succeeded.  | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 28 Aug 2020 13:01:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)            | 28 Aug 2020 13:01:48 |
| Data point term sent to Coder  | System                          | 28 Aug 2020 13:01:03 |
| User entered 'uterine fibroids'  | (b) (4), (b) (6)                | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:55:36 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2005' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:55:36 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:55:36 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                             | 03 Mar 2021 21:55:36 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 2005' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 13:00:27 |



US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 03 Mar 2021 21:55:36 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2005' | System           | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2005' | System           | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2005' | System           | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2005' | System           | 28 Aug 2020 13:00:27 |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 28 Apr 2021 18:23:09 |
| DataPoint Verified.   |                                 | 03 Mar 2021 21:55:20 |
| User signature succeeded.   | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\23.0. | (b) (4)<br>Coder Import (b) (4) | 28 Aug 2020 13:01:48 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)            | 28 Aug 2020 13:01:48 |
| Data point term sent to Coder   | System                          | 28 Aug 2020 13:01:02 |
| User entered 'osteoarthritis bilateral knees'   | (b) (4), (b) (6)                | 28 Aug 2020 13:00:05 |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        |                        | 03 Mar 2021 21:55:20 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'un UNK 1973' | (b) (4), (b) (6)       | 28 Aug 2020 13:00:05 |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 03 Mar 2021 21:55:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 13:00:05 |



**US3292324**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:34:27**

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 03 Mar 2021 21:55:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 28 Aug 2020 13:00:05 |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4)                | 03 Mar 2021 21:55:20 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:00:05 |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 03 Mar 2021 21:55:20 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 13:00:05 |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 1973' | System           | 28 Aug 2020 13:00:05 |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '1973' | System           | 28 Aug 2020 13:00:05 |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 28 Aug 2020 13:00:05 |

US3292324

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 28 Aug 2020 13:00:05 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 28 Apr 2021 18:23:09 |
| DataPoint Verified.  | (b) (4)                         | 03 Mar 2021 21:55:14 |
| User signature succeeded.  | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Femur fracture, LLT: Femur fracture - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 24 Sep 2020 01:06:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)            | 24 Sep 2020 01:06:42 |
| Data point term sent to Coder  | System                          | 24 Sep 2020 01:05:27 |
| User entered 'left femur fracture'   | Dawn Killian (b) (4)<br>(b) (4) | 24 Sep 2020 01:04:41 |



**US3292324**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        | (b) (4), (b) (6)                           | 03 Mar 2021 21:55:14 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered 'UN UNK 2015' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |  | 03 Mar 2021 21:55:14 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 24 Sep 2020 01:04:41 |

**US3292324**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:34:27**

[Condition ongoing at study entry](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 03 Mar 2021 21:55:14 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        | (b) (4)                                    | 03 Mar 2021 21:55:14 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered 'UN UNK 2015' | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       | (b) (4), (b) (6)                           | 03 Mar 2021 21:55:14 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4)<br>Dawn Killian (b) (4)<br>(b) (4) | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2015' | System           | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2015' | System           | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2015' | System           | 24 Sep 2020 01:04:41 |



US3292324

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2015' | System           | 24 Sep 2020 01:04:41 |

US3292324

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:34:27

[Condition](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 28 Apr 2021 18:23:09 |
| DataPoint Verified.   | (b) (4), (b) (6)                | 23 Apr 2021 13:38:44 |
| User signature succeeded.   | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 21 Apr 2021 21:00:34 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)            | 21 Apr 2021 21:00:34 |
| Data point term sent to Coder   | System                          | 21 Apr 2021 21:00:14 |
| User entered 'Osteopenia'   | (b) (4), (b) (6)                | 21 Apr 2021 21:00:02 |

**US3292324**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.        | (b) (4)                | 23 Apr 2021 13:38:49 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered 'un UNK 2014' | (b) (4), (b) (6)       | 21 Apr 2021 21:00:02 |

US3292324

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 23 Apr 2021 13:38:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered '0'          | (b) (4), (b) (6)       | 21 Apr 2021 21:00:02 |

US3292324

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:34:27

[Condition ongoing at study entry](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                        | 23 Apr 2021 13:38:49 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 21 Apr 2021 21:00:02 |

US3292324

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 23 Apr 2021 13:38:49 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Apr 2021 15:51:45 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 21:00:02 |

US3292324

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:34:27

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| DataPoint Verified.       |                             | 23 Apr 2021 13:38:49 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Apr 2021 15:51:45 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 21:00:02 |

US3292324

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'Jan 2014' | System           | 21 Apr 2021 21:00:02 |



US3292324

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:34:27

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '2014' | System           | 21 Apr 2021 21:00:02 |

US3292324

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 21 Apr 2021 21:00:02 |

US3292324

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 21 Apr 2021 21:00:02 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:31:41 |
| User entered 'Yes (Y)'    |                        | 28 Aug 2020 13:01:08                  |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Date of assessment (dd MMM yyyy)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| User signature succeeded.   | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 19:31:41 |
| User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).             | System                      | 28 Aug 2020 13:01:45 |
| Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System). | System                      | 28 Aug 2020 13:01:45 |
| User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).  | System                      | 28 Aug 2020 13:01:45 |
| User entered '27 Aug 2020' reason for change: Data Entry Error  | (b) (4), (b) (6)            | 28 Aug 2020 13:01:45 |
| User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).             | System                      | 28 Aug 2020 13:01:08 |
| User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).  | System                      | 28 Aug 2020 13:01:08 |
| User entered '25 Aug 2020'  | (b) (4), (b) (6)            | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:31:41 |
| User entered '08:44'      |                        | 28 Aug 2020 13:01:08                  |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '27 Aug 2020 08:44' | System           | 28 Aug 2020 13:01:45 |
| User entered '25 Aug 2020 08:44' | System           | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:31:41 |
| User entered '163.0' cm   |                        | 28 Aug 2020 13:01:08                  |
| DataPoint set to visible. | System                 | 27 Aug 2020 15:42:56                  |



US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:31:41 |
| User entered '93.5' kg    |                        | 28 Aug 2020 13:01:08 |
| DataPoint set to visible. | System                 | 27 Aug 2020 15:42:56 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '35.19139'   | System           | 28 Aug 2020 13:01:08 |
| DataPoint set to visible. | System           | 27 Aug 2020 15:42:56 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'kg/m2'      | System           | 28 Aug 2020 13:01:08 |
| DataPoint set to visible. | System           | 27 Aug 2020 15:42:56 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Temperature (xxx.x)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 08 Feb 2021 19:31:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error            | (b) (4), (b) (6)       | 30 Dec 2020 19:50:54 |
| User closed query 'Data is required. Please provide.' (Site from System).              | (b) (4), (b) (6)       | 30 Dec 2020 19:48:19 |
| Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System). | (b) (4), (b) (6)       | 30 Dec 2020 18:05:33 |
| User opened query 'Data is required. Please provide.' System (Site from System).       |                        | 30 Dec 2020 18:05:18 |
| User entered empty; reason for change Data Entry Error                                 | (b) (4), (b) (6)       | 30 Dec 2020 18:05:18 |
| User entered missing code ND - Not Done.   |                        | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Route of measurement](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.   | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.   | (b) (4)                |                      |
|   | (b) (4), (b) (6)       | 08 Feb 2021 19:31:41 |
| User closed query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).            |                        | 23 Dec 2020 13:42:09 |
| Query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' answered with 'update' (Site from DM). | Dawn Killian (b) (4)   | 21 Dec 2020 19:43:59 |
| User entered empty; reason for change Data Entry Error  | (b) (4)                |                      |
|   | Dawn Killian (b) (4)   | 21 Dec 2020 19:43:54 |
| User opened query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).            | (b) (4), (b) (6)       | 14 Dec 2020 17:25:49 |
| User entered 'Other (Other)'  |                        | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[If Other, specify](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.   | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.   | (b) (4)                | 08 Feb 2021 19:31:41 |
| User closed query 'Per CDM: Please remove the data as this field should be "blank". | (b) (4), (b) (6)       | 30 Dec 2020 19:48:21 |
| ' (Site from DM).   |                        |                      |
| Query 'Per CDM: Please remove the data as this field should be "blank".             |                        | 30 Dec 2020 18:05:38 |
| ' answered with 'Completed' (Site from DM).   |                        |                      |
| User entered empty; reason for change Data Entry Error                              |                        | 30 Dec 2020 18:05:18 |
| User opened query 'Per CDM: Please remove the data as this field should be "blank". |                        | 23 Dec 2020 13:42:31 |
| ' (Site from DM).   |                        |                      |
| User entered missing code ND - Not Done.  |                        | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Pulse (xxx)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| User signature succeeded.   | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 19:31:41 |
| User closed query 'Per CDM: Response noted. If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done. please update fields.' (Site from DM).               | (b) (4), (b) (6)            | 30 Dec 2020 22:32:24 |
| Query 'Per CDM: Response noted. If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done. please update fields.' answered with 'Completed' (Site from DM). | (b) (4), (b) (6)            | 30 Dec 2020 19:51:04 |
| User entered missing code ND - Not Done; reason for change Data Entry Error   | (b) (4), (b) (6)            | 30 Dec 2020 19:50:54 |
| User opened query 'Per CDM: Response noted. If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done. please update fields.' (Site from DM).               | (b) (4), (b) (6)            | 30 Dec 2020 19:48:35 |
| User closed query 'Data is required. Please provide.' (Site from System).   | (b) (4), (b) (6)            | 30 Dec 2020 19:48:23 |
| Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System).  | (b) (4), (b) (6)            | 30 Dec 2020 18:05:41 |
| User opened query 'Data is required. Please provide.' System (Site from System).  |                             | 30 Dec 2020 18:05:18 |
| User entered empty; reason for change Data Entry Error  | (b) (4), (b) (6)            | 30 Dec 2020 18:05:18 |
| User entered missing code ND - Not Done.  |                             | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'bpm'  | System           | 30 Dec 2020 19:50:54 |
| User entered empty. | System           | 30 Dec 2020 18:05:18 |
| User entered 'bpm'  | System           | 28 Aug 2020 13:01:08 |



US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 08 Feb 2021 19:31:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error            |                        | 30 Dec 2020 19:50:54 |
| User closed query 'Data is required. Please provide.' (Site from System).              |                        | 30 Dec 2020 19:48:39 |
| Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System). |                        | 30 Dec 2020 18:05:44 |
| User opened query 'Data is required. Please provide.' System (Site from System).       |                        | 30 Dec 2020 18:05:18 |
| User entered empty; reason for change Data Entry Error                                 | (b) (4), (b) (6)       | 30 Dec 2020 18:05:18 |
| User entered missing code ND - Not Done.   |                        | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'breaths/min' | System           | 30 Dec 2020 19:50:54 |
| User entered empty.        | System           | 30 Dec 2020 18:05:18 |
| User entered 'breaths/min' | System           | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Systolic Blood Pressure (xxx)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 08 Feb 2021 19:31:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error            |                        | 30 Dec 2020 19:50:54 |
| User closed query 'Data is required. Please provide.' (Site from System).              |                        | 30 Dec 2020 19:48:41 |
| Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System). |                        | 30 Dec 2020 18:05:47 |
| User opened query 'Data is required. Please provide.' System (Site from System).       |                        | 30 Dec 2020 18:05:18 |
| User entered empty; reason for change Data Entry Error                                 | (b) (4), (b) (6)       | 30 Dec 2020 18:05:18 |
| User entered missing code ND - Not Done.   |                        | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'mmHg' | System           | 30 Dec 2020 19:50:54 |
| User entered empty. | System           | 30 Dec 2020 18:05:18 |
| User entered 'mmHg' | System           | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Diastolic Blood Pressure (xxx)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 08 Feb 2021 19:31:41 |
| User entered missing code ND - Not Done; reason for change Data Entry Error            |                        | 30 Dec 2020 19:50:54 |
| User closed query 'Data is required. Please provide.' (Site from System).              |                        | 30 Dec 2020 19:48:44 |
| Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System). |                        | 30 Dec 2020 18:05:51 |
| User opened query 'Data is required. Please provide.' System (Site from System).       |                        | 30 Dec 2020 18:05:18 |
| User entered empty; reason for change Data Entry Error                                 | (b) (4), (b) (6)       | 30 Dec 2020 18:05:18 |
| User entered missing code ND - Not Done.   |                        | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'mmHg' | System           | 30 Dec 2020 19:50:54 |
| User entered empty. | System           | 30 Dec 2020 18:05:18 |
| User entered 'mmHg' | System           | 28 Aug 2020 13:01:08 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |

US3292324

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |



US3292324

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:34:27

[Was the physical examination performed?](#)

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:33:12 |
| User entered 'Yes (Y)'    |                        | 28 Aug 2020 13:01:58                  |

US3292324

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:34:27

Date of examination (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4)                |                      |
|                            | (b) (4), (b) (6)       | 08 Feb 2021 19:33:12 |
| User entered '27 Aug 2020' |                        | 28 Aug 2020 13:01:58 |

US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:34:27

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)                            |
|----------------------------|------------------------|---------------------------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09                  |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.        | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:32:17 |
| User entered '27 Aug 2020' |                        | 28 Aug 2020 13:02:26                  |

US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:34:27

[Is the participant of childbearing potential?](#)

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:32:17 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:02:26                  |

US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:34:27

[If No, what is the reason?](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.                              | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.                                    | (b) (4), (b) (6)       | 08 Feb 2021 19:32:17 |
| User entered 'Surgically sterile (SURGICALLY STERILE)' |                        | 28 Aug 2020 13:02:26 |

**US3292324**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 16:34:27**

[If Partner medically sterile or Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                | 08 Feb 2021 19:32:17 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:02:26 |

**US3292324**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                      | User                   | Time (GMT)                            |
|----------------------------|------------------------|---------------------------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09                  |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.        | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:32:17 |
| User entered 'un UNK 2005' |                        | 28 Aug 2020 13:02:26                  |

US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:34:27

Date of surgery unknown

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:17 |
| User entered '0'          |                        | 28 Aug 2020 13:02:26 |



US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:17 |
| User entered empty.       |                        | 28 Aug 2020 13:02:26 |

US3292324

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:34:27

Date of last menstruation unknown

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:32:17 |
| User entered '0'          |                        | 28 Aug 2020 13:02:26                  |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

**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 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:44 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

**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 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:44 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

**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 18:23:09                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:32:44 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:02:46                  |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

**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 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:44 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

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 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                | 08 Feb 2021 19:32:44 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

[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 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:44 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:02:46 |



US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

**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 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 19:32:44 |
| User entered 'No (N)'     |                             | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

[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 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:44 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

**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 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:44 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

**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 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:44 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

**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 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:44 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

[Other](#)

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:32:44 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:02:46                  |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

[Specify](#)

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:32:44 |
| User entered empty.       |                        | 28 Aug 2020 13:02:46                  |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

No Risk Identified

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 13:02:46 |



US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

Resides in Nursing Home or Assisted Living Facility

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:44 |
| User entered '0'          |                        | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

**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 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:44 |
| User entered '0'          |                        | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

**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 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                | 08 Feb 2021 19:32:44 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

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 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:44 |
| User entered '0'          |                        | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:32:44 |
| User entered 'l'          |                        | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

[Other](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 13:02:46 |

US3292324

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:34:27

[Specify](#)

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:32:44 |
| User entered empty.       |                        | 28 Aug 2020 13:02:46                  |

US3292324

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:33:22 |
| User entered 'Yes (Y)'    |                        | 28 Aug 2020 13:03:24 |



US3292324

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

Visit date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)                            |
|----------------------------|------------------------|---------------------------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24                  |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.        | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:33:22 |
| User entered '27 Aug 2020' |                        | 28 Aug 2020 13:03:24                  |

US3292324

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.      | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.            | (b) (4)                |                      |
|                                | (b) (4), (b) (6)       | 08 Feb 2021 19:33:22 |
| User entered 'Clinic (Clinic)' |                        | 28 Aug 2020 13:03:24 |

**US3292324**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:34:27**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'VISIT1' | System           | 28 Aug 2020 13:03:24 |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:34:27

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4)           | 16 Apr 2021 14:42:31 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 08 Feb 2021 19:35:07 |
| User entered '27 AUG 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 27 Aug 2020 15:09:35 |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4)           | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 08 Feb 2021 19:35:05 |
| User entered '188281'     | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 27 Aug 2020 15:09:35 |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:34:27

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

| Audit                         | User                             | Time (GMT)           |
|-------------------------------|----------------------------------|----------------------|
| Data hard locked.             | (b) (4), (b) (6)                 | 25 Apr 2021 12:41:24 |
| User signature succeeded.     | Douglas Denham (b) (4)           | 16 Apr 2021 14:42:31 |
| DataPoint Verified.           | (b) (4)<br>(b) (4), (b) (6)      | 08 Feb 2021 19:35:04 |
| User entered '>=65 years (3)' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 27 Aug 2020 15:09:35 |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:34:27

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)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:35:02 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:03:50 |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:34:27

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)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:35:01 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:03:50 |



**US3292324**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:34:59 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 28 Aug 2020 13:03:50 |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:34:27

Diabetes (Type I, Type 2, or gestational)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 25 Apr 2021 12:41:24 |
| User signature succeeded.   | Douglas Denham (b) (4)      | 16 Apr 2021 14:42:31 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 12 Apr 2021 17:19:11 |
| User closed query 'Answer does not match source. Please review and update accordingly.' (Site from CRA).                    |                             | 12 Apr 2021 17:19:09 |
| Query 'Answer does not match source. Please review and update accordingly.' answered with 'source updated' (Site from CRA). | Antonio Gutierrez (b) (4)   | 24 Mar 2021 16:49:41 |
| User opened query 'Answer does not match source. Please review and update accordingly.' (Site from CRA).                    | (b) (4), (b) (6)            | 08 Feb 2021 19:34:53 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Dawn Killian (b) (4)        | 31 Aug 2020 19:02:07 |
| User entered 'No (N)'   | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 13:03:50 |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:34:27

[Liver Disease](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:34:55 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:03:50 |

US3292324

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:34:27

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

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.   | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.   | (b) (4)                | 08 Feb 2021 19:34:57 |
| User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).             | (b) (4), (b) (6)       | 11 Dec 2020 16:08:21 |
| Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated' (Site from DM). | Dawn Killian (b) (4)   | 07 Dec 2020 23:20:22 |
| User entered 'No (N)'   | (b) (4)                | 07 Dec 2020 23:20:14 |
| User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).             | (b) (4), (b) (6)       | 01 Dec 2020 22:47:28 |
| Amendment Manager: DataPoint set to visible.  | System                 | 19 Sep 2020 08:12:41 |
| Amendment Manager inserted this DataPoint.  | System                 | 19 Sep 2020 08:12:40 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:34:27

[Height](#)

| Audit                                    | User                   | Time (GMT)                            |
|--|------------------------|---------------------------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24                  |
| User signature succeeded.                | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.                      | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:35:33 |
| User entered missing code ND - Not Done. |                        | 28 Aug 2020 13:08:19                  |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:34:27

Weight

| Audit                                    | User                   | Time (GMT)                            |
|--|------------------------|---------------------------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24                  |
| User signature succeeded.                | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.                      | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:35:35 |
| User entered missing code ND - Not Done. |                        | 28 Aug 2020 13:08:19                  |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:34:27

[Height](#)

| Audit                                    | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.                | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.                      | (b) (4)                | 08 Feb 2021 19:35:33 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6)       | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:34:27

[Weight](#)

| Audit                                    | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.                | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.                      | (b) (4)                | 08 Feb 2021 19:35:35 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6)       | 28 Aug 2020 13:08:19 |



US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User accepted default value 'Pre-Dose (PREDOSE)' |                  | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 12 Apr 2021 17:22:31 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 25 Apr 2021 12:41:24 |
| DataPoint Verified.        |                             | 12 Apr 2021 17:22:31 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '27 Aug 2020' | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| DataPoint Verified.       |                        | 12 Apr 2021 17:22:31 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '09:25'      | (b) (4), (b) (6)       | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered '27 Aug 2020 09:25' | System           | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| DataPoint Verified.       |                        | 12 Apr 2021 17:22:31 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '036.8' C    | (b) (4), (b) (6)       | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Route of measurement](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| DataPoint Verified.        |                        | 12 Apr 2021 17:22:31 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6)       | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 25 Apr 2021 12:41:24 |
| DataPoint Verified.       |                             | 12 Apr 2021 17:22:31 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 13:08:19 |



US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 25 Apr 2021 12:41:24 |
| DataPoint Verified.       |                             | 12 Apr 2021 17:22:31 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '065'        | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'bpm' | System           | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 25 Apr 2021 12:41:24 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 12 Apr 2021 17:22:31 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '016'        | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'breaths/min' | System           | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

Systolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 25 Apr 2021 12:41:24 |
| DataPoint Verified.       |                             | 12 Apr 2021 17:22:31 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '131'        | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'mmHg' | System           | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

Diastolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 25 Apr 2021 12:41:24 |
| DataPoint Verified.       |                             | 12 Apr 2021 17:22:31 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '081'        | (b) (4)<br>(b) (4), (b) (6) | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'mmHg' | System           | 28 Aug 2020 13:08:19 |



US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:34:27

[Height](#)

| Audit                                    | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.                | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.                      | (b) (4)                | 08 Feb 2021 19:35:33 |
| User entered missing code ND - Not Done. | (b) (4), (b) (6)       | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:34:27

Weight

| Audit                                    | User                   | Time (GMT)                            |
|--|------------------------|---------------------------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24                  |
| User signature succeeded.                | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.                      | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:35:35 |
| User entered missing code ND - Not Done. |                        | 28 Aug 2020 13:08:19                  |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User accepted default value 'Post-Dose (POSTDOSE)' |                  | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:36:34 |
| User entered 'Yes (Y)'    |                        | 28 Aug 2020 13:08:19                  |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4)                |                      |
|                            | (b) (4), (b) (6)       | 08 Feb 2021 19:36:35 |
| User entered '27 Aug 2020' |                        | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                | 08 Feb 2021 19:36:37 |
| User entered '11:00'      | (b) (4), (b) (6)       | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered '27 Aug 2020 11:00' | System           | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:36:38 |
| User entered '036.7' C    | (b) (4), (b) (6)       | 28 Aug 2020 13:08:19 |



US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Route of measurement](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4)                | 08 Feb 2021 19:36:41 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6)       | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                | 08 Feb 2021 19:36:42 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Pulse \(xxx\)](#)

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:36:46 |
| User entered '066'        |                        | 28 Aug 2020 13:08:19                  |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'bpm' | System           | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:36:48 |
| User entered '012'        |                        | 28 Aug 2020 13:08:19                  |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'breaths/min' | System           | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

Systolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:36:50 |
| User entered '120'        |                        | 28 Aug 2020 13:08:19                  |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'mmHg' | System           | 28 Aug 2020 13:08:19 |



US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

Diastolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                | 08 Feb 2021 19:36:52 |
| User entered '076'        | (b) (4), (b) (6)       | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'mmHg' | System           | 28 Aug 2020 13:08:19 |

US3292324

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:34:27

[Was the physical examination performed?](#)

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:38:06 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:08:41                  |

US3292324

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:34:27

Date of examination (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                | 08 Feb 2021 19:38:06 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:08:41 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

[Was study treatment given?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:38:12 |
| User entered 'Yes (Y)'    | Nathan Cortez (b) (4)  | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

[If No, reason not given](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:38:12 |
| User entered empty.       | Nathan Cortez (b) (4)  | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

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)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:38:12 |
| User entered empty.       | Nathan Cortez (b) (4)  | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 27 Aug 2020 15:43:21 |



US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:38:12 |
| User entered '27 Aug 2020' | Nathan Cortez (b) (4)  | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 19:38:12 |
| User entered '10:30'      | Nathan Cortez (b) (4)       | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered '27 Aug 2020 10:30' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

[Which arm was used to give treatment?](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 25 Apr 2021 12:41:24 |
| User signature succeeded.          | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| DataPoint Verified.                | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 19:38:12 |
| User entered 'Left Arm (LEFT ARM)' | Nathan Cortez (b) (4)       | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| DataPoint Verified. |                  | 08 Feb 2021 19:38:12 |
| User entered 'ONCE' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'INTRAMUSCULAR' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                | 08 Feb 2021 19:40:39 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 28 Aug 2020 13:10:39 |

US3292324

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

Collection date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4)                | 08 Feb 2021 19:40:39 |
| User entered '27 Aug 2020' | (b) (4), (b) (6)       | 28 Aug 2020 13:10:39 |



**US3292324**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                     | User                   | Time (GMT)                            |
|---------------------------|------------------------|---------------------------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24                  |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.       | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:40:39 |
| User entered '09:36'      |                        | 28 Aug 2020 13:10:39                  |

US3292324

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered '27 Aug 2020 09:36' | System           | 28 Aug 2020 13:10:39 |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:34:27

Collection date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)                            |
|----------------------------|------------------------|---------------------------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24                  |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51                  |
| DataPoint Verified.        | (b) (4)                | (b) (4), (b) (6) 08 Feb 2021 19:40:43 |
| User entered '27 Aug 2020' |                        | 28 Aug 2020 13:10:54                  |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:34:27

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' |                  | 28 Aug 2020 13:10:54 |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:34:27

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:40:43 |
| User entered 'Yes (Y)'    |                        | 28 Aug 2020 13:10:54 |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:34:27

Collection time (00:00 - 23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:40:43 |
| User entered '09:47'      |                        | 28 Aug 2020 13:10:54 |

**US3292324**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered '27 Aug 2020 09:47' | System           | 28 Aug 2020 13:10:54 |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:34:27

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' |                  | 28 Aug 2020 13:10:54 |



US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:34:27

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:40:43 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:10:54 |

US3292324

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:34:27

Collection time (00:00 - 23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:40:43 |
| User entered empty.       |                        | 28 Aug 2020 13:10:54 |

**US3292324**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered empty. | System           | 28 Aug 2020 13:10:54 |

US3292324

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:40:46 |
| User entered 'Yes (Y)'    |                        | 28 Aug 2020 13:10:59 |

US3292324

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'l'  | System           | 28 Aug 2020 13:10:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

TIMEPOINT

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:03:23', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '979191b1-1b26-41d1-af4b-5fec81e5f0c2' | System           | 27 Aug 2020 16:04:15 |
| User entered 'Yes (Y)'   | System           | 27 Aug 2020 16:04:15 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:03:31', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '979191b1-1b26-41d1-af4b-5fec81e5f0c2' | System           | 27 Aug 2020 16:04:15 |
| User entered '98.0'  | System           | 27 Aug 2020 16:04:15 |



US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:03:36', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '979191b1-1b26-41d1-af4b-5fec81e5f0c2' | System           | 27 Aug 2020 16:04:15 |
| User entered 'No (N)'  | System           | 27 Aug 2020 16:04:15 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:03:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '979191b1-1b26-41d1-af4b-5fec81e5f0c2' | System           | 27 Aug 2020 16:04:15 |
| User entered '27 Aug 2020 11:03'   | System           | 27 Aug 2020 16:04:15 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Aug 2020 10:50' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Aug 2020 13:20' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.                                | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 1, after vaccination (at home)' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:17', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0f4874c4-7620-4a4e-8110-e0bfb1c1aeaa' User entered 'Yes (Y)' | System           | 28 Aug 2020 00:29:46 |
|   | System           | 28 Aug 2020 00:29:46 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:28', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0f4874c4-7620-4a4e-8110-e0bfb1c1aeaa' User entered '98.8' | System           | 28 Aug 2020 00:29:46 |
|  | System           | 28 Aug 2020 00:29:46 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0f4874c4-7620-4a4e-8110-e0bfb1c1aeaa' | System           | 28 Aug 2020 00:29:46 |
| User entered 'No (N)'  | System           | 28 Aug 2020 00:29:46 |



US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0f4874c4-7620-4a4e-8110-e0bfb1c1aeaa' | System           | 28 Aug 2020 00:29:46 |
| User entered '27 Aug 2020 19:29'   | System           | 28 Aug 2020 00:29:46 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Aug 2020 14:15' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '28 Aug 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 2' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:52:37', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'a1456587-b9ee-4cc1-a1cf-eb83054ba076' | System           | 28 Aug 2020 23:52:58 |
| User entered 'Yes (Y)'   | System           | 28 Aug 2020 23:52:58 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:52:44', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'a1456587-b9ee-4cc1-a1cf-eb83054ba076' User entered '98.8' | System           | 28 Aug 2020 23:52:58 |
|  | System           | 28 Aug 2020 23:52:58 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:52:50', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'a1456587-b9ee-4cc1-a1cf-eb83054ba076' | System           | 28 Aug 2020 23:52:58 |
| User entered 'No (N)'  | System           | 28 Aug 2020 23:52:58 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:52:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'a1456587-b9ee-4cc1-a1cf-eb83054ba076' User entered '28 Aug 2020 18:52' | System           | 28 Aug 2020 23:52:58 |
|   | System           | 28 Aug 2020 23:52:58 |



US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '28 Aug 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '29 Aug 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 3' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:40:47', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e788488e-ba41-4a61-b5b8-8be666886c01' User entered 'Yes (Y)' | System           | 30 Aug 2020 12:41:28 |
|   | System           | 30 Aug 2020 12:41:28 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e788488e-ba41-4a61-b5b8-8be666886c01' User entered '97.7' | System           | 30 Aug 2020 12:41:28 |
|  | System           | 30 Aug 2020 12:41:28 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:18', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e788488e-ba41-4a61-b5b8-8be666886c01' | System           | 30 Aug 2020 12:41:28 |
| User entered 'No (N)'  | System           | 30 Aug 2020 12:41:28 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:26', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e788488e-ba41-4a61-b5b8-8be666886c01' User entered '30 Aug 2020 07:41' | System           | 30 Aug 2020 12:41:28 |
|   | System           | 30 Aug 2020 12:41:28 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '29 Aug 2020 12:00' | System           | 27 Aug 2020 15:43:21 |



US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '30 Aug 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 4' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:58:36', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8acb70dd-ca55-4707-9042-9d1e3cd4c58a' User entered 'Yes (Y)' | System           | 31 Aug 2020 00:58:59 |
|   | System           | 31 Aug 2020 00:58:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:58:46', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8acb70dd-ca55-4707-9042-9d1e3cd4c58a' User entered '99.0' | System           | 31 Aug 2020 00:58:59 |
|  | System           | 31 Aug 2020 00:58:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:58:49', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8acb70dd-ca55-4707-9042-9d1e3cd4c58a' User entered 'No (N)' | System           | 31 Aug 2020 00:58:59 |
|  | System           | 31 Aug 2020 00:58:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:58:56', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8acb70dd-ca55-4707-9042-9d1e3cd4c58a' User entered '30 Aug 2020 19:58' | System           | 31 Aug 2020 00:58:59 |
|   | System           | 31 Aug 2020 00:58:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '30 Aug 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '31 Aug 2020 11:59' | System           | 27 Aug 2020 15:43:21 |



US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 5' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:08', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0e30235c-22ca-43c1-ad7a-a2abdb9b162d' User entered 'Yes (Y)' | System           | 01 Sep 2020 01:07:29 |
|   | System           | 01 Sep 2020 01:07:29 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0e30235c-22ca-43c1-ad7a-a2abdb9b162d' User entered '97.8' | System           | 01 Sep 2020 01:07:29 |
|  | System           | 01 Sep 2020 01:07:29 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:23', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0e30235c-22ca-43c1-ad7a-a2abdb9b162d' User entered 'No (N)' | System           | 01 Sep 2020 01:07:29 |
|  | System           | 01 Sep 2020 01:07:29 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:26', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0e30235c-22ca-43c1-ad7a-a2abdb9b162d' User entered '31 Aug 2020 20:07' | System           | 01 Sep 2020 01:07:29 |
|   | System           | 01 Sep 2020 01:07:29 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '31 Aug 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '01 Sep 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 6' | System           | 27 Aug 2020 15:43:21 |



US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:54:13', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4f9b8de-8a4c-4001-bb3f-ed178adf6191' | System           | 02 Sep 2020 01:54:41 |
| User entered 'Yes (Y)'   | System           | 02 Sep 2020 01:54:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:54:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4f9b8de-8a4c-4001-bb3f-ed178adf6191' User entered '98.1' | System           | 02 Sep 2020 01:54:41 |
|  | System           | 02 Sep 2020 01:54:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:54:29', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4f9b8de-8a4c-4001-bb3f-ed178adf6191' | System           | 02 Sep 2020 01:54:41 |
| User entered 'No (N)'  | System           | 02 Sep 2020 01:54:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:54:39', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4f9b8de-8a4c-4001-bb3f-ed178adf6191' | System           | 02 Sep 2020 01:54:41 |
| User entered '01 Sep 2020 20:54'   | System           | 02 Sep 2020 01:54:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '01 Sep 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '02 Sep 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 7' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:45:47', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '469c7d17-9f94-448d-930d-d58eeeb612d3' User entered 'Yes (Y)' | System           | 03 Sep 2020 00:46:38 |
|   | System           | 03 Sep 2020 00:46:38 |



US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:22', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '469c7d17-9f94-448d-930d-d58eeeb612d3' User entered '98.2' | System           | 03 Sep 2020 00:46:38 |
|  | System           | 03 Sep 2020 00:46:38 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:26', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '469c7d17-9f94-448d-930d-d58eeeb612d3' | System           | 03 Sep 2020 00:46:38 |
| User entered 'No (N)'  | System           | 03 Sep 2020 00:46:38 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '469c7d17-9f94-448d-930d-d58eeeb612d3' User entered '02 Sep 2020 19:46' | System           | 03 Sep 2020 00:46:38 |
|   | System           | 03 Sep 2020 00:46:38 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '02 Sep 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '03 Sep 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:04', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c4341e38-81c0-4949-8969-0d0958724f84' User entered 'None (1)' | System           | 27 Aug 2020 16:04:23 |
|  | System           | 27 Aug 2020 16:04:23 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:07', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c4341e38-81c0-4949-8969-0d0958724f84' User entered 'No (N)' | System           | 27 Aug 2020 16:04:23 |
|  | System           | 27 Aug 2020 16:04:23 |



US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:10', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c4341e38-81c0-4949-8969-0d0958724f84' User entered 'No (N)' | System           | 27 Aug 2020 16:04:23 |
|  | System           | 27 Aug 2020 16:04:23 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c4341e38-81c0-4949-8969-0d0958724f84' User entered 'None (1)' | System           | 27 Aug 2020 16:04:23 |
|  | System           | 27 Aug 2020 16:04:23 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c4341e38-81c0-4949-8969-0d0958724f84' User entered '27 Aug 2020 11:04' | System           | 27 Aug 2020 16:04:23 |
|   | System           | 27 Aug 2020 16:04:23 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Aug 2020 10:50' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Aug 2020 13:20' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.                                | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 1, after vaccination (at home)' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4e4cd01-933b-495a-a233-40fadab277c8' | System           | 28 Aug 2020 00:30:07 |
| User entered 'None (1)'  | System           | 28 Aug 2020 00:30:07 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:51', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4e4cd01-933b-495a-a233-40fadab277c8' | System           | 28 Aug 2020 00:30:07 |
| User entered 'No (N)'  | System           | 28 Aug 2020 00:30:07 |



US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:54', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4e4cd01-933b-495a-a233-40fadab277c8' | System           | 28 Aug 2020 00:30:07 |
| User entered 'No (N)'  | System           | 28 Aug 2020 00:30:07 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:29:59', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4e4cd01-933b-495a-a233-40fadab277c8' | System           | 28 Aug 2020 00:30:07 |
| User entered 'None (1)'  | System           | 28 Aug 2020 00:30:07 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:03', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd4e4cd01-933b-495a-a233-40fadab277c8' User entered '27 Aug 2020 19:30' | System           | 28 Aug 2020 00:30:07 |
|   | System           | 28 Aug 2020 00:30:07 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Aug 2020 14:15' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '28 Aug 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 2' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:12', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '1a0d9601-9259-4884-9dd7-dc70ea6f8c20' | System           | 28 Aug 2020 23:53:41 |
| User entered 'Does not interfere with activity (2)'  | System           | 28 Aug 2020 23:53:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:17', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '1a0d9601-9259-4884-9dd7-dc70ea6f8c20' User entered 'No (N)' | System           | 28 Aug 2020 23:53:41 |
|  | System           | 28 Aug 2020 23:53:41 |



US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '1a0d9601-9259-4884-9dd7-dc70ea6f8c20' | System           | 28 Aug 2020 23:53:41 |
| User entered 'No (N)'  | System           | 28 Aug 2020 23:53:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:29', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '1a0d9601-9259-4884-9dd7-dc70ea6f8c20' | System           | 28 Aug 2020 23:53:41 |
| User entered 'None (1)'  | System           | 28 Aug 2020 23:53:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:37', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '1a0d9601-9259-4884-9dd7-dc70ea6f8c20' User entered '28 Aug 2020 18:53' | System           | 28 Aug 2020 23:53:41 |
|   | System           | 28 Aug 2020 23:53:41 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '28 Aug 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '29 Aug 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 3' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2fcf7b67-cfda-48ab-99e8-9865e8a6c5c9' | System           | 30 Aug 2020 12:41:49 |
| User entered 'None (1)'  | System           | 30 Aug 2020 12:41:49 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:34', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2fcf7b67-cfda-48ab-99e8-9865e8a6c5c9' | System           | 30 Aug 2020 12:41:49 |
| User entered 'No (N)'  | System           | 30 Aug 2020 12:41:49 |



US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:37', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2fcf7b67-cfda-48ab-99e8-9865e8a6c5c9' | System           | 30 Aug 2020 12:41:49 |
| User entered 'No (N)'  | System           | 30 Aug 2020 12:41:49 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2fcf7b67-cfda-48ab-99e8-9865e8a6c5c9' | System           | 30 Aug 2020 12:41:49 |
| User entered 'None (1)'  | System           | 30 Aug 2020 12:41:49 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:45', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2fcf7b67-cfda-48ab-99e8-9865e8a6c5c9' User entered '30 Aug 2020 07:41' | System           | 30 Aug 2020 12:41:49 |
|   | System           | 30 Aug 2020 12:41:49 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '29 Aug 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '30 Aug 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 4' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:06', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '72ee69fe-3ff0-4d32-bd6f-2dd77128a1c7' | System           | 31 Aug 2020 00:59:27 |
| User entered 'None (1)'  | System           | 31 Aug 2020 00:59:27 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:09', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '72ee69fe-3ff0-4d32-bd6f-2dd77128a1c7' | System           | 31 Aug 2020 00:59:27 |
| User entered 'No (N)'  | System           | 31 Aug 2020 00:59:27 |



US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:12', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '72ee69fe-3ff0-4d32-bd6f-2dd77128a1c7' | System           | 31 Aug 2020 00:59:27 |
| User entered 'No (N)'  | System           | 31 Aug 2020 00:59:27 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:18', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '72ee69fe-3ff0-4d32-bd6f-2dd77128a1c7' | System           | 31 Aug 2020 00:59:27 |
| User entered 'None (1)'  | System           | 31 Aug 2020 00:59:27 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:22', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '72ee69fe-3ff0-4d32-bd6f-2dd77128a1c7' | System           | 31 Aug 2020 00:59:27 |
| User entered '30 Aug 2020 19:59'   | System           | 31 Aug 2020 00:59:27 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '30 Aug 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '31 Aug 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 5' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '4201afb6-09c6-4212-839b-48eb1754be6d' User entered 'None (1)' | System           | 01 Sep 2020 01:07:57 |
|  | System           | 01 Sep 2020 01:07:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '4201afb6-09c6-4212-839b-48eb1754be6d' User entered 'No (N)' | System           | 01 Sep 2020 01:07:57 |
|  | System           | 01 Sep 2020 01:07:57 |



US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '4201afb6-09c6-4212-839b-48eb1754be6d' User entered 'No (N)' | System           | 01 Sep 2020 01:07:57 |
|  | System           | 01 Sep 2020 01:07:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '4201afb6-09c6-4212-839b-48eb1754be6d' User entered 'None (1)' | System           | 01 Sep 2020 01:07:57 |
|  | System           | 01 Sep 2020 01:07:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:07:55', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '4201afb6-09c6-4212-839b-48eb1754be6d' User entered '31 Aug 2020 20:07' | System           | 01 Sep 2020 01:07:57 |
|   | System           | 01 Sep 2020 01:07:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '31 Aug 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '01 Sep 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 6' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:54:55', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ac295084-defb-4598-a1ef-6cc27fac160e' User entered 'None (1)' | System           | 02 Sep 2020 01:55:51 |
|  | System           | 02 Sep 2020 01:55:51 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:55:11', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ac295084-defb-4598-a1ef-6cc27fac160e' User entered 'No (N)' | System           | 02 Sep 2020 01:55:51 |
|  | System           | 02 Sep 2020 01:55:51 |



US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:55:28', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ac295084-defb-4598-a1ef-6cc27fac160e' User entered 'No (N)' | System           | 02 Sep 2020 01:55:51 |
|  | System           | 02 Sep 2020 01:55:51 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:55:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ac295084-defb-4598-a1ef-6cc27fac160e' User entered 'None (1)' | System           | 02 Sep 2020 01:55:51 |
|  | System           | 02 Sep 2020 01:55:51 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:55:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ac295084-defb-4598-a1ef-6cc27fac160e' User entered '01 Sep 2020 20:55' | System           | 02 Sep 2020 01:55:51 |
|   | System           | 02 Sep 2020 01:55:51 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '01 Sep 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '02 Sep 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 7' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:40', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '36c211c5-ed35-415f-bc34-c7fee1ddf55c' | System           | 03 Sep 2020 00:46:57 |
| User entered 'None (1)'  | System           | 03 Sep 2020 00:46:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '36c211c5-ed35-415f-bc34-c7fee1ddf55c' User entered 'No (N)' | System           | 03 Sep 2020 00:46:57 |
|  | System           | 03 Sep 2020 00:46:57 |



US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:45', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '36c211c5-ed35-415f-bc34-c7fee1ddf55c' User entered 'No (N)' | System           | 03 Sep 2020 00:46:57 |
|  | System           | 03 Sep 2020 00:46:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '36c211c5-ed35-415f-bc34-c7fee1ddf55c' | System           | 03 Sep 2020 00:46:57 |
| User entered 'None (1)'  | System           | 03 Sep 2020 00:46:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '36c211c5-ed35-415f-bc34-c7fee1ddf55c' User entered '02 Sep 2020 19:46' | System           | 03 Sep 2020 00:46:57 |
|   | System           | 03 Sep 2020 00:46:57 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '02 Sep 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '03 Sep 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:26', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' User entered 'None (0)' | System           | 27 Aug 2020 16:04:59 |
|  | System           | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' User entered 'None (0)' | System           | 27 Aug 2020 16:04:59 |
|  | System           | 27 Aug 2020 16:04:59 |



US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' User entered 'None (0)' | System           | 27 Aug 2020 16:04:59 |
|  | System           | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:38', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' User entered 'None (0)' | System           | 27 Aug 2020 16:04:59 |
|  | System           | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:40', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' User entered 'None (0)' | System           | 27 Aug 2020 16:04:59 |
|  | System           | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' User entered 'None (0)' | System           | 27 Aug 2020 16:04:59 |
|  | System           | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:47', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' User entered 'No (N)' | System           | 27 Aug 2020 16:04:59 |
|  | System           | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T11:04:54', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6bbb7bd-a04d-4cfc-995e-b12e29bf08e4' User entered '27 Aug 2020 11:04' | System           | 27 Aug 2020 16:04:59 |
|   | System           | 27 Aug 2020 16:04:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Aug 2020 10:50' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Aug 2020 13:20' | System           | 27 Aug 2020 15:43:21 |



US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.                                | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 1, after vaccination (at home)' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' User entered 'None (0)' | System           | 28 Aug 2020 00:30:50 |
|  | System           | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:21', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' User entered 'None (0)' | System           | 28 Aug 2020 00:30:50 |
|  | System           | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:26', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' User entered 'None (0)' | System           | 28 Aug 2020 00:30:50 |
|  | System           | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:29', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' User entered 'None (0)' | System           | 28 Aug 2020 00:30:50 |
|  | System           | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' User entered 'None (0)' | System           | 28 Aug 2020 00:30:50 |
|  | System           | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' User entered 'None (0)' | System           | 28 Aug 2020 00:30:50 |
|  | System           | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' User entered 'No (N)' | System           | 28 Aug 2020 00:30:50 |
|  | System           | 28 Aug 2020 00:30:50 |



US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-27T19:30:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'c8261811-37f0-4568-b3eb-ce5d394c3acc' User entered '27 Aug 2020 19:30' | System           | 28 Aug 2020 00:30:50 |
|   | System           | 28 Aug 2020 00:30:50 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Aug 2020 14:15' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '28 Aug 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 2' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:43', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' User entered 'None (0)' | System           | 28 Aug 2020 23:54:45 |
|  | System           | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:54:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' User entered 'None (0)' | System           | 28 Aug 2020 23:54:45 |
|  | System           | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:53:59', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' User entered 'None (0)' | System           | 28 Aug 2020 23:54:45 |
|  | System           | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:54:03', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' User entered 'None (0)' | System           | 28 Aug 2020 23:54:45 |
|  | System           | 28 Aug 2020 23:54:45 |



US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:54:06', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' User entered 'None (0)' | System           | 28 Aug 2020 23:54:45 |
|  | System           | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:54:09', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' User entered 'None (0)' | System           | 28 Aug 2020 23:54:45 |
|  | System           | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:54:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' User entered 'No (N)' | System           | 28 Aug 2020 23:54:45 |
|  | System           | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-28T18:54:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0d43fc48-07c3-4c32-8378-c17f5a701e1f' User entered '28 Aug 2020 18:54' | System           | 28 Aug 2020 23:54:45 |
|   | System           | 28 Aug 2020 23:54:45 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '28 Aug 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '29 Aug 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 3' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:50', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' User entered 'None (0)' | System           | 30 Aug 2020 12:44:20 |
|  | System           | 30 Aug 2020 12:44:20 |



US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:55', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' User entered 'None (0)' | System           | 30 Aug 2020 12:44:20 |
|  | System           | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:41:58', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' User entered 'None (0)' | System           | 30 Aug 2020 12:44:20 |
|  | System           | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:42:03', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' User entered 'None (0)' | System           | 30 Aug 2020 12:44:20 |
|  | System           | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:42:07', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' User entered 'None (0)' | System           | 30 Aug 2020 12:44:20 |
|  | System           | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:42:11', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' User entered 'None (0)' | System           | 30 Aug 2020 12:44:20 |
|  | System           | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:42:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' User entered 'No (N)' | System           | 30 Aug 2020 12:44:20 |
|  | System           | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T07:42:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4597f86-1b31-4831-9a25-62f1f617be3b' User entered '30 Aug 2020 07:42' | System           | 30 Aug 2020 12:44:20 |
|   | System           | 30 Aug 2020 12:44:20 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '29 Aug 2020 12:00' | System           | 27 Aug 2020 15:43:21 |



US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '30 Aug 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 4' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' | System           | 31 Aug 2020 00:59:59 |
| User entered 'None (0)'  | System           | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:38', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' User entered 'None (0)' | System           | 31 Aug 2020 00:59:59 |
|  | System           | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:40', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' User entered 'None (0)' | System           | 31 Aug 2020 00:59:59 |
|  | System           | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' User entered 'None (0)' | System           | 31 Aug 2020 00:59:59 |
|  | System           | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:45', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' | System           | 31 Aug 2020 00:59:59 |
| User entered 'None (0)'  | System           | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:47', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' User entered 'None (0)' | System           | 31 Aug 2020 00:59:59 |
|  | System           | 31 Aug 2020 00:59:59 |



US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:50', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' | System           | 31 Aug 2020 00:59:59 |
| User entered 'No (N)'  | System           | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-30T19:59:55', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'f24e3c8b-86cd-45f0-8e20-aa41a2f38452' | System           | 31 Aug 2020 00:59:59 |
| User entered '30 Aug 2020 19:59'   | System           | 31 Aug 2020 00:59:59 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '30 Aug 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '31 Aug 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 5' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:08:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' User entered 'None (0)' | System           | 01 Sep 2020 01:10:17 |
|  | System           | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:08:03', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' User entered 'None (0)' | System           | 01 Sep 2020 01:10:17 |
|  | System           | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:08:07', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' User entered 'None (0)' | System           | 01 Sep 2020 01:10:17 |
|  | System           | 01 Sep 2020 01:10:17 |



US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:08:09', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' User entered 'None (0)' | System           | 01 Sep 2020 01:10:17 |
|  | System           | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:08:21', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' User entered 'None (0)' | System           | 01 Sep 2020 01:10:17 |
|  | System           | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:08:34', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' User entered 'None (0)' | System           | 01 Sep 2020 01:10:17 |
|  | System           | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:10:07', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' User entered 'No (N)' | System           | 01 Sep 2020 01:10:17 |
|  | System           | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-08-31T20:10:15', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '13115607-9a91-4065-8ddb-32fa226bbaa0' User entered '31 Aug 2020 20:10' | System           | 01 Sep 2020 01:10:17 |
|   | System           | 01 Sep 2020 01:10:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '31 Aug 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '01 Sep 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 6' | System           | 27 Aug 2020 15:43:21 |



US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:56:08', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' User entered 'None (0)' | System           | 02 Sep 2020 01:57:17 |
|  | System           | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:56:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' User entered 'None (0)' | System           | 02 Sep 2020 01:57:17 |
|  | System           | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:56:20', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' User entered 'None (0)' | System           | 02 Sep 2020 01:57:17 |
|  | System           | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:56:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' User entered 'None (0)' | System           | 02 Sep 2020 01:57:17 |
|  | System           | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:56:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' User entered 'None (0)' | System           | 02 Sep 2020 01:57:17 |
|  | System           | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:57:04', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' User entered 'None (0)' | System           | 02 Sep 2020 01:57:17 |
|  | System           | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:57:07', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' User entered 'No (N)' | System           | 02 Sep 2020 01:57:17 |
|  | System           | 02 Sep 2020 01:57:17 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-01T20:57:15', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '863ca415-9fbe-4d19-aae3-d0d4a73b8c3b' User entered '01 Sep 2020 20:57' | System           | 02 Sep 2020 01:57:17 |
|   | System           | 02 Sep 2020 01:57:17 |



US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '01 Sep 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '02 Sep 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 7' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:46:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' User entered 'None (0)' | System           | 03 Sep 2020 00:47:18 |
|  | System           | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' User entered 'None (0)' | System           | 03 Sep 2020 00:47:18 |
|  | System           | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:02', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' User entered 'None (0)' | System           | 03 Sep 2020 00:47:18 |
|  | System           | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:05', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' User entered 'None (0)' | System           | 03 Sep 2020 00:47:18 |
|  | System           | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:08', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' User entered 'None (0)' | System           | 03 Sep 2020 00:47:18 |
|  | System           | 03 Sep 2020 00:47:18 |



US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:10', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' User entered 'None (0)' | System           | 03 Sep 2020 00:47:18 |
|  | System           | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:13', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' User entered 'No (N)' | System           | 03 Sep 2020 00:47:18 |
|  | System           | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-02T19:47:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b54e5137-dd2c-4928-afdc-0f738478b4e0' User entered '02 Sep 2020 19:47' | System           | 03 Sep 2020 00:47:18 |
|   | System           | 03 Sep 2020 00:47:18 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '02 Sep 2020 12:00' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '03 Sep 2020 11:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Was Contact Attempted?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:42:52 |
| User entered 'Yes (Y)'    | Kristy Trevino (b) (4) | 03 Sep 2020 16:52:15 |

US3292324

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit   | User                      | Time (GMT)           |
|---|---------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)          | 25 Apr 2021 12:41:24 |
| User signature succeeded.                                     | Douglas Denham (b) (4)    | 23 Feb 2021 14:15:51 |
| DataPoint Verified.   | (b) (4), (b) (6)          | 08 Feb 2021 19:42:52 |
| User entered '03 Sep 2020' reason for change: New Information | Antonio Gutierrez (b) (4) | 10 Nov 2020 15:47:03 |
| User entered '3 Sep 2020'                                     | Kristy Trevino (b) (4)    | 03 Sep 2020 16:52:15 |

US3292324

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

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

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.                        | (b) (4), (b) (6)       | 08 Feb 2021 19:42:52 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) | 03 Sep 2020 16:52:15 |



US3292324

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:42:52 |
| User entered empty.       | Kristy Trevino (b) (4) | 03 Sep 2020 16:52:15 |

US3292324

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:42:56 |
| User entered 'Yes (Y)'    | Kristy Trevino (b) (4) | 03 Sep 2020 16:52:23 |

US3292324

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'l'  | System           | 03 Sep 2020 16:52:23 |

**US3292324**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:34:27**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 19:45:23 |
| User entered 'Yes (Y)'    | Antonio Gutierrez (b) (4)   | 06 Nov 2020 15:47:25 |

US3292324

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                      | User                      | Time (GMT)           |
|----------------------------|---------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)          | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4)    | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)          | 08 Feb 2021 19:45:23 |
| User entered '10 Sep 2020' | Antonio Gutierrez (b) (4) | 06 Nov 2020 15:47:25 |

US3292324

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)          | 25 Apr 2021 12:41:24 |
| User signature succeeded.                          | Douglas Denham (b) (4)    | 23 Feb 2021 14:15:51 |
| DataPoint Verified.                                | (b) (4), (b) (6)          | 08 Feb 2021 19:45:23 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | Antonio Gutierrez (b) (4) | 06 Nov 2020 15:47:25 |

US3292324

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 08 Feb 2021 19:45:23 |
| User entered 'Attempts were made, but staff unable to contact patient' | Antonio Gutierrez (b) (4)   | 06 Nov 2020 15:47:25 |

**US3292324**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:45:33 |
| User entered 'Yes (Y)'    | Nathan Cortez (b) (4)  | 24 Sep 2020 15:04:34 |



US3292324

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'l'  | System           | 24 Sep 2020 15:04:34 |

**US3292324**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:34:27**

[Was Contact Attempted?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:46:01 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 02 Oct 2020 16:54:14 |

US3292324

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:46:01 |
| User entered '18 Sep 2020' | Gerardo Pena (b) (4)   | 02 Oct 2020 16:54:14 |

US3292324

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

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

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.                        | (b) (4), (b) (6)       | 08 Feb 2021 19:46:01 |
| User entered 'Contact Made (CONTACT MADE)' | Gerardo Pena (b) (4)   | 02 Oct 2020 16:54:14 |

US3292324

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:46:01 |
| User entered empty.       | Gerardo Pena (b) (4)   | 02 Oct 2020 16:54:14 |

US3292324

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:46:05 |
| User entered 'Yes (Y)'    | Nathan Cortez (b) (4)  | 24 Sep 2020 15:04:42 |

US3292324

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'l'  | System           | 24 Sep 2020 15:04:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:46:36 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 24 Sep 2020 16:06:41 |



US3292324

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

Visit date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:46:36 |
| User entered '24 Sep 2020' | Gerardo Pena (b) (4)   | 24 Sep 2020 16:06:41 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.      | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.            | (b) (4), (b) (6)       | 08 Feb 2021 19:46:36 |
| User entered 'Clinic (Clinic)' | Gerardo Pena (b) (4)   | 24 Sep 2020 16:06:41 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'VISIT2' | System           | 24 Sep 2020 16:06:41 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                | 25 Apr 2021 12:41:24 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Gerardo Pena (b) (4)<br>(b) (4) | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '24 Sep 2020' | Gerardo Pena (b) (4)   | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '09:15'      | Gerardo Pena (b) (4)   | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered '24 Sep 2020 09:15' | System           | 24 Sep 2020 16:07:42 |



US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '36.9' C     | Gerardo Pena (b) (4)   | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Route of measurement](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered 'Oral (Oral)' | Gerardo Pena (b) (4)   | 24 Sep 2020 16:07:42 |

**US3292324**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:34:27**

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered empty.       | Gerardo Pena (b) (4)   | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Pulse \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '67'         | Gerardo Pena (b) (4)   | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'bpm' | System           | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '12'         | Gerardo Pena (b) (4)   | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'breaths/min' | System           | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

Systolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '115'        | Gerardo Pena (b) (4)   | 24 Sep 2020 16:07:42 |



US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'mmHg' | System           | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '64'         | Gerardo Pena (b) (4)   | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:34:27

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'mmHg' | System           | 24 Sep 2020 16:07:42 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                | 25 Apr 2021 12:41:24 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Gerardo Pena (b) (4)<br>(b) (4) | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '24 Sep 2020' | Gerardo Pena (b) (4)   | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '10:29'      | Gerardo Pena (b) (4)   | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered '24 Sep 2020 10:29' | System           | 24 Sep 2020 16:10:59 |



US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '36.6' C     | Gerardo Pena (b) (4)   | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Route of measurement](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered 'Oral (Oral)' | Gerardo Pena (b) (4)   | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered empty.       | Gerardo Pena (b) (4)   | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Pulse \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '68'         | Gerardo Pena (b) (4)   | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'bpm' | System           | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '12'         | Gerardo Pena (b) (4)   | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'breaths/min' | System           | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

Systolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '117'        | Gerardo Pena (b) (4)   | 24 Sep 2020 16:10:59 |



US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'mmHg' | System           | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

Diastolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:47:46 |
| User entered '74'         | Gerardo Pena (b) (4)   | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:34:27

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'mmHg' | System           | 24 Sep 2020 16:10:59 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:34:27

[Was the physical examination performed?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 08 Feb 2021 19:48:35 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)<br>(b) (4) | 24 Sep 2020 16:11:22 |

**US3292324**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:48:35 |
| User entered '24 Sep 2020' | Gerardo Pena (b) (4)   | 24 Sep 2020 16:11:22 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

[Was study treatment given?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:48:51 |
| User entered 'Yes (Y)'    | Nathan Cortez (b) (4)  | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

[If No, reason not given](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:48:51 |
| User entered empty.       | Nathan Cortez (b) (4)  | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

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)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:48:51 |
| User entered empty.       | Nathan Cortez (b) (4)  | 24 Sep 2020 15:05:06 |



US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:48:51 |
| User entered '24 Sep 2020' | Nathan Cortez (b) (4)  | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:48:51 |
| User entered '09:59'      | Nathan Cortez (b) (4)  | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered '24 Sep 2020 09:59' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

[Which arm was used to give treatment?](#)

| Audit                              | User                   | Time (GMT)           |
|------------------------------------|------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.          | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.                | (b) (4), (b) (6)       | 08 Feb 2021 19:48:51 |
| User entered 'Left Arm (LEFT ARM)' | Nathan Cortez (b) (4)  | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| DataPoint Verified. |                  | 08 Feb 2021 19:48:51 |
| User entered 'ONCE' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:34:27

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'INTRAMUSCULAR' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:48:07 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 24 Sep 2020 16:11:37 |



US3292324

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

Collection date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:48:07 |
| User entered '24 Sep 2020' | Gerardo Pena (b) (4)   | 24 Sep 2020 16:11:37 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

Collection time (00:00-23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:48:07 |
| User entered '09:22'      | Gerardo Pena (b) (4)   | 24 Sep 2020 16:11:37 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered '24 Sep 2020 09:22' | System           | 24 Sep 2020 16:11:37 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:34:27

Collection date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:48:18 |
| User entered '24 Sep 2020' | Gerardo Pena (b) (4)   | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:34:27

[Lab Test](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 25 Apr 2021 12:41:24 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Gerardo Pena (b) (4)<br>(b) (4) | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:34:27

[Was the sample collected?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 08 Feb 2021 19:48:18 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)<br>(b) (4) | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:34:27

Collection time (00:00 - 23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:48:18 |
| User entered '09:40'      | Gerardo Pena (b) (4)   | 24 Sep 2020 16:11:56 |

**US3292324**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered '24 Sep 2020 09:40' | System           | 24 Sep 2020 16:11:56 |



**US3292324**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Lab Test](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 25 Apr 2021 12:41:24 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Gerardo Pena (b) (4)<br>(b) (4) | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:34:27

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:48:18 |
| User entered 'No (N)'     | Gerardo Pena (b) (4)   | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:34:27

Collection time (00:00 - 23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:48:18 |
| User entered empty.       | Gerardo Pena (b) (4)   | 24 Sep 2020 16:11:56 |

**US3292324**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered empty. | System           | 24 Sep 2020 16:11:56 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:48:23 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 24 Sep 2020 16:12:02 |

US3292324

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'I'  | System           | 24 Sep 2020 16:12:02 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

TIMEPOINT

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:31:39', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e412fe7c-0b74-4b2e-9247-7f8259a46ef0' User entered 'Yes (Y)' | System           | 24 Sep 2020 15:32:02 |
|   | System           | 24 Sep 2020 15:32:02 |



US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:31:47', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e412fe7c-0b74-4b2e-9247-7f8259a46ef0' User entered '97.8' | System           | 24 Sep 2020 15:32:02 |
|  | System           | 24 Sep 2020 15:32:02 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:31:54', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e412fe7c-0b74-4b2e-9247-7f8259a46ef0' | System           | 24 Sep 2020 15:32:02 |
| User entered 'No (N)'  | System           | 24 Sep 2020 15:32:02 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e412fe7c-0b74-4b2e-9247-7f8259a46ef0' User entered '24 Sep 2020 10:32' | System           | 24 Sep 2020 15:32:02 |
|   | System           | 24 Sep 2020 15:32:02 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '24 Sep 2020 10:19' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '24 Sep 2020 12:49' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.                                | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 1, after vaccination (at home)' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:48:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '31a605f0-70bb-4e14-a7e7-7cd768c0d85b' User entered 'Yes (Y)' | System           | 25 Sep 2020 00:49:14 |
|   | System           | 25 Sep 2020 00:49:14 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:05', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '31a605f0-70bb-4e14-a7e7-7cd768c0d85b' User entered '97.9' | System           | 25 Sep 2020 00:49:14 |
|  | System           | 25 Sep 2020 00:49:14 |



US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:08', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '31a605f0-70bb-4e14-a7e7-7cd768c0d85b' User entered 'No (N)' | System           | 25 Sep 2020 00:49:14 |
|  | System           | 25 Sep 2020 00:49:14 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:11', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '31a605f0-70bb-4e14-a7e7-7cd768c0d85b' User entered '24 Sep 2020 19:49' | System           | 25 Sep 2020 00:49:14 |
|   | System           | 25 Sep 2020 00:49:14 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '24 Sep 2020 13:44' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '25 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 2' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:30:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ef10d865-5992-4de1-8aa7-0c51f04b065f' User entered 'Yes (Y)' | System           | 25 Sep 2020 23:32:37 |
|   | System           | 25 Sep 2020 23:32:37 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:12', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ef10d865-5992-4de1-8aa7-0c51f04b065f' User entered '99.6' | System           | 25 Sep 2020 23:32:37 |
|  | System           | 25 Sep 2020 23:32:37 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ef10d865-5992-4de1-8aa7-0c51f04b065f' User entered 'Yes (Y)' | System           | 25 Sep 2020 23:32:37 |
|   | System           | 25 Sep 2020 23:32:37 |



US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit   | User                 | Time (GMT)           |
|---|----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)     | 05 Mar 2021 00:18:10 |
| 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 'will ask at next phone call' (Site from System). | (b) (4), (b) (6)     | 11 Nov 2020 12:20:43 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'will ask at next phone call' (Site from System).  | Dawn Killian (b) (4) | 28 Sep 2020 14:59:46 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).  | (b) (4)              |                      |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:27', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ef10d865-5992-4de1-8aa7-0c51f04b065f'  | System               | 25 Sep 2020 23:32:37 |
| User entered '1'  | System               | 25 Sep 2020 23:32:37 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:27', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ef10d865-5992-4de1-8aa7-0c51f04b065f' User entered '0' | System           | 25 Sep 2020 23:32:37 |
|   | System           | 25 Sep 2020 23:32:37 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ef10d865-5992-4de1-8aa7-0c51f04b065f' User entered '25 Sep 2020 18:32' | System           | 25 Sep 2020 23:32:37 |
|   | System           | 25 Sep 2020 23:32:37 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '25 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '26 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 3' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7cf767d6-5415-4f58-83ee-fee5296b3607' User entered 'Yes (Y)' | System           | 27 Sep 2020 16:06:47 |
|   | System           | 27 Sep 2020 16:06:47 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:37', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7cf767d6-5415-4f58-83ee-fee5296b3607' User entered '98.6' | System           | 27 Sep 2020 16:06:47 |
|  | System           | 27 Sep 2020 16:06:47 |



US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7cf767d6-5415-4f58-83ee-fee5296b3607' | System           | 27 Sep 2020 16:06:47 |
| User entered 'No (N)'  | System           | 27 Sep 2020 16:06:47 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:44', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7cf767d6-5415-4f58-83ee-fee5296b3607' | System           | 27 Sep 2020 16:06:47 |
| User entered '27 Sep 2020 11:06'   | System           | 27 Sep 2020 16:06:47 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '26 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 4' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:10', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8f405322-374a-4dd1-9059-fdbe38e9537f' User entered 'Yes (Y)' | System           | 28 Sep 2020 01:12:33 |
|   | System           | 28 Sep 2020 01:12:33 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:21', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8f405322-374a-4dd1-9059-fdbe38e9537f' User entered '98.6' | System           | 28 Sep 2020 01:12:33 |
|  | System           | 28 Sep 2020 01:12:33 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8f405322-374a-4dd1-9059-fdbe38e9537f' User entered 'No (N)' | System           | 28 Sep 2020 01:12:33 |
|  | System           | 28 Sep 2020 01:12:33 |



US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:28', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8f405322-374a-4dd1-9059-fdbe38e9537f' User entered '27 Sep 2020 20:12' | System           | 28 Sep 2020 01:12:33 |
|   | System           | 28 Sep 2020 01:12:33 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '28 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 5' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T18:59:44', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '11d848b9-e425-4fb1-8e43-52a9b3b24d14' User entered 'Yes (Y)' | System           | 28 Sep 2020 23:59:59 |
|   | System           | 28 Sep 2020 23:59:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T18:59:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '11d848b9-e425-4fb1-8e43-52a9b3b24d14' User entered '98.4' | System           | 28 Sep 2020 23:59:59 |
|  | System           | 28 Sep 2020 23:59:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T18:59:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '11d848b9-e425-4fb1-8e43-52a9b3b24d14' User entered 'No (N)' | System           | 28 Sep 2020 23:59:59 |
|  | System           | 28 Sep 2020 23:59:59 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T18:59:55', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '11d848b9-e425-4fb1-8e43-52a9b3b24d14' User entered '28 Sep 2020 18:59' | System           | 28 Sep 2020 23:59:59 |
|   | System           | 28 Sep 2020 23:59:59 |



US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '28 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '29 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 6' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:00:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '35cdf34c-4d59-468c-ae6-781133513dd4' | System           | 30 Sep 2020 12:01:10 |
| User entered 'Yes (Y)'  | System           | 30 Sep 2020 12:01:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:02', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '35cdf34c-4d59-468c-ace6-781133513dd4' User entered '98.4' | System           | 30 Sep 2020 12:01:10 |
|  | System           | 30 Sep 2020 12:01:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:06', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '35cdf34c-4d59-468c-ace6-781133513dd4' | System           | 30 Sep 2020 12:01:10 |
| User entered 'No (N)'  | System           | 30 Sep 2020 12:01:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:09', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '35cdf34c-4d59-468c-ae6-781133513dd4' User entered '30 Sep 2020 07:01' | System           | 30 Sep 2020 12:01:10 |
|  | System           | 30 Sep 2020 12:01:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '29 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |



US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '30 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 7' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:01:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'df3f73bc-b603-4e39-ac60-4ac28ab47dcc' User entered 'Yes (Y)' | System           | 01 Oct 2020 12:02:07 |
|   | System           | 01 Oct 2020 12:02:07 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:01:58', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'df3f73bc-b603-4e39-ac60-4ac28ab47dcc' User entered '98.0' | System           | 01 Oct 2020 12:02:07 |
|  | System           | 01 Oct 2020 12:02:07 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:01', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'df3f73bc-b603-4e39-ac60-4ac28ab47dcc' User entered 'No (N)' | System           | 01 Oct 2020 12:02:07 |
|  | System           | 01 Oct 2020 12:02:07 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:04', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'df3f73bc-b603-4e39-ac60-4ac28ab47dcc' User entered '01 Oct 2020 07:02' | System           | 01 Oct 2020 12:02:07 |
|   | System           | 01 Oct 2020 12:02:07 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '30 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '01 Oct 2020 11:59' | System           | 24 Sep 2020 15:05:06 |



US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

TIMEPOINT

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:06', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '239fd9e5-97c5-405d-ade8-e441e6b435cb' User entered 'None (1)' | System           | 24 Sep 2020 15:32:21 |
|  | System           | 24 Sep 2020 15:32:21 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:09', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '239fd9e5-97c5-405d-ade8-e441e6b435cb' User entered 'No (N)' | System           | 24 Sep 2020 15:32:21 |
|  | System           | 24 Sep 2020 15:32:21 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:11', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '239fd9e5-97c5-405d-ade8-e441e6b435cb' User entered 'No (N)' | System           | 24 Sep 2020 15:32:21 |
|  | System           | 24 Sep 2020 15:32:21 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:15', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '239fd9e5-97c5-405d-ade8-e441e6b435cb' User entered 'None (1)' | System           | 24 Sep 2020 15:32:21 |
|  | System           | 24 Sep 2020 15:32:21 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:18', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '239fd9e5-97c5-405d-ade8-e441e6b435cb' User entered '24 Sep 2020 10:32' | System           | 24 Sep 2020 15:32:21 |
|   | System           | 24 Sep 2020 15:32:21 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '24 Sep 2020 10:19' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '24 Sep 2020 12:49' | System           | 24 Sep 2020 15:05:06 |



US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.                                | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 1, after vaccination (at home)' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '30d70f4c-b342-4380-acfe-dade29cdb707' | System           | 25 Sep 2020 00:49:27 |
| User entered 'None (1)'  | System           | 25 Sep 2020 00:49:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:18', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '30d70f4c-b342-4380-acfe-dade29cdb707' | System           | 25 Sep 2020 00:49:27 |
| User entered 'No (N)'  | System           | 25 Sep 2020 00:49:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:20', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '30d70f4c-b342-4380-acfe-dade29cdb707' | System           | 25 Sep 2020 00:49:27 |
| User entered 'No (N)'  | System           | 25 Sep 2020 00:49:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:23', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '30d70f4c-b342-4380-acfe-dade29cdb707' | System           | 25 Sep 2020 00:49:27 |
| User entered 'None (1)'  | System           | 25 Sep 2020 00:49:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '30d70f4c-b342-4380-acfe-dade29cdb707' User entered '24 Sep 2020 19:49' | System           | 25 Sep 2020 00:49:27 |
|   | System           | 25 Sep 2020 00:49:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '24 Sep 2020 13:44' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '25 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |



US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 2' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5c387c2d-a09b-424b-9c1d-567dd96936d8' | System           | 25 Sep 2020 23:33:01 |
| User entered 'None (1)'  | System           | 25 Sep 2020 23:33:01 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:44', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5c387c2d-a09b-424b-9c1d-567dd96936d8' User entered 'No (N)' | System           | 25 Sep 2020 23:33:01 |
|  | System           | 25 Sep 2020 23:33:01 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:49', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5c387c2d-a09b-424b-9c1d-567dd96936d8' | System           | 25 Sep 2020 23:33:01 |
| User entered 'No (N)'  | System           | 25 Sep 2020 23:33:01 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5c387c2d-a09b-424b-9c1d-567dd96936d8' | System           | 25 Sep 2020 23:33:01 |
| User entered 'None (1)'  | System           | 25 Sep 2020 23:33:01 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:32:56', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5c387c2d-a09b-424b-9c1d-567dd96936d8' User entered '25 Sep 2020 18:32' | System           | 25 Sep 2020 23:33:01 |
|   | System           | 25 Sep 2020 23:33:01 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '25 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '26 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |



US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 3' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:49', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5ca01f82-42d6-45d9-96e6-75b49968b956' User entered 'None (1)' | System           | 27 Sep 2020 16:07:12 |
|  | System           | 27 Sep 2020 16:07:12 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:51', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5ca01f82-42d6-45d9-96e6-75b49968b956' User entered 'No (N)' | System           | 27 Sep 2020 16:07:12 |
|  | System           | 27 Sep 2020 16:07:12 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:06:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5ca01f82-42d6-45d9-96e6-75b49968b956' User entered 'No (N)' | System           | 27 Sep 2020 16:07:12 |
|  | System           | 27 Sep 2020 16:07:12 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:05', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5ca01f82-42d6-45d9-96e6-75b49968b956' User entered 'None (1)' | System           | 27 Sep 2020 16:07:12 |
|  | System           | 27 Sep 2020 16:07:12 |

**US3292324**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:34:27**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:08', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '5ca01f82-42d6-45d9-96e6-75b49968b956' User entered '27 Sep 2020 11:07' | System           | 27 Sep 2020 16:07:12 |
|   | System           | 27 Sep 2020 16:07:12 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '26 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |



US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 4' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'afc91674-b162-4fc8-825f-86d28451a263' | System           | 28 Sep 2020 01:12:48 |
| User entered 'None (1)'  | System           | 28 Sep 2020 01:12:48 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'afc91674-b162-4fc8-825f-86d28451a263' | System           | 28 Sep 2020 01:12:48 |
| User entered 'No (N)'  | System           | 28 Sep 2020 01:12:48 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:38', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'afc91674-b162-4fc8-825f-86d28451a263' | System           | 28 Sep 2020 01:12:48 |
| User entered 'No (N)'  | System           | 28 Sep 2020 01:12:48 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:40', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'afc91674-b162-4fc8-825f-86d28451a263' | System           | 28 Sep 2020 01:12:48 |
| User entered 'None (1)'  | System           | 28 Sep 2020 01:12:48 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:44', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'afc91674-b162-4fc8-825f-86d28451a263' | System           | 28 Sep 2020 01:12:48 |
| User entered '27 Sep 2020 20:12'   | System           | 28 Sep 2020 01:12:48 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '28 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |



US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 5' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T18:59:59', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2faa67b2-6bd5-441d-b626-3c64698c063c' User entered 'None (1)' | System           | 29 Sep 2020 00:00:15 |
|  | System           | 29 Sep 2020 00:00:15 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:02', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2faa67b2-6bd5-441d-b626-3c64698c063c' User entered 'No (N)' | System           | 29 Sep 2020 00:00:15 |
|  | System           | 29 Sep 2020 00:00:15 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:05', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2faa67b2-6bd5-441d-b626-3c64698c063c' User entered 'No (N)' | System           | 29 Sep 2020 00:00:15 |
|  | System           | 29 Sep 2020 00:00:15 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:10', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2faa67b2-6bd5-441d-b626-3c64698c063c' User entered 'None (1)' | System           | 29 Sep 2020 00:00:15 |
|  | System           | 29 Sep 2020 00:00:15 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:12', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '2faa67b2-6bd5-441d-b626-3c64698c063c' User entered '28 Sep 2020 19:00' | System           | 29 Sep 2020 00:00:15 |
|   | System           | 29 Sep 2020 00:00:15 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '28 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '29 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |



US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 6' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:12', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'af40d496-f541-4bbd-b64a-98164b324983' | System           | 30 Sep 2020 12:01:27 |
| User entered 'None (1)'  | System           | 30 Sep 2020 12:01:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'af40d496-f541-4bbd-b64a-98164b324983' | System           | 30 Sep 2020 12:01:27 |
| User entered 'No (N)'  | System           | 30 Sep 2020 12:01:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:20', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'af40d496-f541-4bbd-b64a-98164b324983' User entered 'No (N)' | System           | 30 Sep 2020 12:01:27 |
|  | System           | 30 Sep 2020 12:01:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:23', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'af40d496-f541-4bbd-b64a-98164b324983' | System           | 30 Sep 2020 12:01:27 |
| User entered 'None (1)'  | System           | 30 Sep 2020 12:01:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'af40d496-f541-4bbd-b64a-98164b324983' User entered '30 Sep 2020 07:01' | System           | 30 Sep 2020 12:01:27 |
|   | System           | 30 Sep 2020 12:01:27 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '29 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '30 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |



US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 7' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:08', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '432e94ea-d37a-4dfd-be4e-bed1711bf712' | System           | 01 Oct 2020 12:02:22 |
| User entered 'None (1)'  | System           | 01 Oct 2020 12:02:22 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:11', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '432e94ea-d37a-4dfd-be4e-bed1711bf712' | System           | 01 Oct 2020 12:02:22 |
| User entered 'No (N)'  | System           | 01 Oct 2020 12:02:22 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:13', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '432e94ea-d37a-4dfd-be4e-bed1711bf712' | System           | 01 Oct 2020 12:02:22 |
| User entered 'No (N)'  | System           | 01 Oct 2020 12:02:22 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:17', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '432e94ea-d37a-4dfd-be4e-bed1711bf712' | System           | 01 Oct 2020 12:02:22 |
| User entered 'None (1)'  | System           | 01 Oct 2020 12:02:22 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '432e94ea-d37a-4dfd-be4e-bed1711bf712' User entered '01 Oct 2020 07:02' | System           | 01 Oct 2020 12:02:22 |
|   | System           | 01 Oct 2020 12:02:22 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '30 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '01 Oct 2020 11:59' | System           | 24 Sep 2020 15:05:06 |



US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:22', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered 'None (0)' | System           | 24 Sep 2020 15:32:46 |
|  | System           | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:27', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered 'None (0)' | System           | 24 Sep 2020 15:32:46 |
|  | System           | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:29', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered 'None (0)' | System           | 24 Sep 2020 15:32:46 |
|  | System           | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:31', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered 'None (0)' | System           | 24 Sep 2020 15:32:46 |
|  | System           | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered 'None (0)' | System           | 24 Sep 2020 15:32:46 |
|  | System           | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered 'None (0)' | System           | 24 Sep 2020 15:32:46 |
|  | System           | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:40', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered 'No (N)' | System           | 24 Sep 2020 15:32:46 |
|  | System           | 24 Sep 2020 15:32:46 |



US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T10:32:43', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6ac8a9a3-c944-4d3e-9e56-8827a22d43ec' User entered '24 Sep 2020 10:32' | System           | 24 Sep 2020 15:32:46 |
|   | System           | 24 Sep 2020 15:32:46 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '24 Sep 2020 10:19' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '24 Sep 2020 12:49' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.                                | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 1, after vaccination (at home)' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:30', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' User entered 'None (0)' | System           | 25 Sep 2020 00:49:56 |
|  | System           | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' User entered 'None (0)' | System           | 25 Sep 2020 00:49:56 |
|  | System           | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:34', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' User entered 'None (0)' | System           | 25 Sep 2020 00:49:56 |
|  | System           | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:36', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' User entered 'None (0)' | System           | 25 Sep 2020 00:49:56 |
|  | System           | 25 Sep 2020 00:49:56 |



US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:38', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' User entered 'None (0)' | System           | 25 Sep 2020 00:49:56 |
|  | System           | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' User entered 'None (0)' | System           | 25 Sep 2020 00:49:56 |
|  | System           | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:51', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' User entered 'No (N)' | System           | 25 Sep 2020 00:49:56 |
|  | System           | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-24T19:49:54', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fd5a6084-3a1c-4a00-87db-c9f48eba259b' User entered '24 Sep 2020 19:49' | System           | 25 Sep 2020 00:49:56 |
|   | System           | 25 Sep 2020 00:49:56 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '24 Sep 2020 13:44' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '25 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 2' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:33:07', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' User entered 'None (0)' | System           | 25 Sep 2020 23:34:39 |
|  | System           | 25 Sep 2020 23:34:39 |



US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:34:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' User entered 'None (0)' | System           | 25 Sep 2020 23:34:39 |
|  | System           | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:33:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' User entered 'None (0)' | System           | 25 Sep 2020 23:34:39 |
|  | System           | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:33:27', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' User entered 'None (0)' | System           | 25 Sep 2020 23:34:39 |
|  | System           | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:33:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' | System           | 25 Sep 2020 23:34:39 |
| User entered 'Some interference with activity or >2 episodes/24 hours (2)'   | System           | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:33:54', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' | System           | 25 Sep 2020 23:34:39 |
| User entered 'Some interference with activity not requiring medical attention (2)'   | System           | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:34:01', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' User entered 'No (N)' | System           | 25 Sep 2020 23:34:39 |
|  | System           | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-25T18:34:34', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd186d701-30a0-44f8-85f8-4480016497b0' User entered '25 Sep 2020 18:34' | System           | 25 Sep 2020 23:34:39 |
|   | System           | 25 Sep 2020 23:34:39 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '25 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |



US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '26 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 3' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:14', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' User entered 'None (0)' | System           | 27 Sep 2020 16:07:35 |
|  | System           | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' User entered 'None (0)' | System           | 27 Sep 2020 16:07:35 |
|  | System           | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:18', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' User entered 'None (0)' | System           | 27 Sep 2020 16:07:35 |
|  | System           | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' User entered 'None (0)' | System           | 27 Sep 2020 16:07:35 |
|  | System           | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:26', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' User entered 'None (0)' | System           | 27 Sep 2020 16:07:35 |
|  | System           | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:28', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' User entered 'None (0)' | System           | 27 Sep 2020 16:07:35 |
|  | System           | 27 Sep 2020 16:07:35 |



US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:30', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' User entered 'No (N)' | System           | 27 Sep 2020 16:07:35 |
|  | System           | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T11:07:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10002523-a045-4881-adb6-69946a7839f0' User entered '27 Sep 2020 11:07' | System           | 27 Sep 2020 16:07:35 |
|   | System           | 27 Sep 2020 16:07:35 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '26 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 4' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:47', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' User entered 'None (0)' | System           | 28 Sep 2020 01:13:05 |
|  | System           | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:50', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' User entered 'None (0)' | System           | 28 Sep 2020 01:13:05 |
|  | System           | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' User entered 'None (0)' | System           | 28 Sep 2020 01:13:05 |
|  | System           | 28 Sep 2020 01:13:05 |



US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:54', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' User entered 'None (0)' | System           | 28 Sep 2020 01:13:05 |
|  | System           | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:56', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' | System           | 28 Sep 2020 01:13:05 |
| User entered 'None (0)'  | System           | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:12:58', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' User entered 'None (0)' | System           | 28 Sep 2020 01:13:05 |
|  | System           | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:13:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' | System           | 28 Sep 2020 01:13:05 |
| User entered 'No (N)'  | System           | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-27T20:13:02', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '865ed253-3a16-4568-963d-e93d83599bb3' | System           | 28 Sep 2020 01:13:05 |
| User entered '27 Sep 2020 20:13'   | System           | 28 Sep 2020 01:13:05 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '27 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '28 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 5' | System           | 24 Sep 2020 15:05:06 |



US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System           | 29 Sep 2020 00:00:38 |
| User entered 'None (0)'  | System           | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:18', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' User entered 'None (0)' | System           | 29 Sep 2020 00:00:38 |
|  | System           | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:20', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' User entered 'None (0)' | System           | 29 Sep 2020 00:00:38 |
|  | System           | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:22', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System           | 29 Sep 2020 00:00:38 |
| User entered 'None (0)'  | System           | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System           | 29 Sep 2020 00:00:38 |
| User entered 'None (0)'  | System           | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:28', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System           | 29 Sep 2020 00:00:38 |
| User entered 'None (0)'  | System           | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:31', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System           | 29 Sep 2020 00:00:38 |
| User entered 'No (N)'  | System           | 29 Sep 2020 00:00:38 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-28T19:00:36', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '8ae44fff-59b8-4b07-8b4e-8d4ea7c70325' | System           | 29 Sep 2020 00:00:38 |
| User entered '28 Sep 2020 19:00'   | System           | 29 Sep 2020 00:00:38 |



US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '28 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '29 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 6' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:36', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' User entered 'None (0)' | System           | 30 Sep 2020 12:02:10 |
|  | System           | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' User entered 'None (0)' | System           | 30 Sep 2020 12:02:10 |
|  | System           | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:45', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' User entered 'None (0)' | System           | 30 Sep 2020 12:02:10 |
|  | System           | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' User entered 'None (0)' | System           | 30 Sep 2020 12:02:10 |
|  | System           | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' User entered 'None (0)' | System           | 30 Sep 2020 12:02:10 |
|  | System           | 30 Sep 2020 12:02:10 |



US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:01:55', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' User entered 'None (0)' | System           | 30 Sep 2020 12:02:10 |
|  | System           | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:02:04', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' User entered 'No (N)' | System           | 30 Sep 2020 12:02:10 |
|  | System           | 30 Sep 2020 12:02:10 |

**US3292324**

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

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

**Generated On: 09 Jun 2021 16:34:27**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-09-30T07:02:06', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '526fb48c-0c72-4784-8d49-685e2a942c54' User entered '30 Sep 2020 07:02' | System           | 30 Sep 2020 12:02:10 |
|   | System           | 30 Sep 2020 12:02:10 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '29 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '30 Sep 2020 11:59' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.   | System           | 24 Sep 2020 15:05:06 |
| User entered 'Day 7' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:23', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' User entered 'None (0)' | System           | 01 Oct 2020 12:02:45 |
|  | System           | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' User entered 'None (0)' | System           | 01 Oct 2020 12:02:45 |
|  | System           | 01 Oct 2020 12:02:45 |



US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:28', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' User entered 'None (0)' | System           | 01 Oct 2020 12:02:45 |
|  | System           | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:31', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' User entered 'None (0)' | System           | 01 Oct 2020 12:02:45 |
|  | System           | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' User entered 'None (0)' | System           | 01 Oct 2020 12:02:45 |
|  | System           | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' User entered 'None (0)' | System           | 01 Oct 2020 12:02:45 |
|  | System           | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:38', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' | System           | 01 Oct 2020 12:02:45 |
| User entered 'No (N)'  | System           | 01 Oct 2020 12:02:45 |

**US3292324**

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

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

**Generated On: 09 Jun 2021 16:34:27**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-01T07:02:40', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '7ea9a32b-26b9-4bc2-b355-021453a31055' User entered '01 Oct 2020 07:02' | System           | 01 Oct 2020 12:02:45 |
|   | System           | 01 Oct 2020 12:02:45 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '30 Sep 2020 12:00' | System           | 24 Sep 2020 15:05:06 |

US3292324

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:34:27

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| User entered '01 Oct 2020 11:59' | System           | 24 Sep 2020 15:05:06 |



**US3292324**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:34:27**

[Was Contact Attempted?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4)<br>(b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)                  | 08 Feb 2021 19:49:27 |
| User entered 'Yes (Y)'    |                                   | 01 Oct 2020 18:46:22 |

US3292324

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:49:27 |
| User entered '1 Oct 2020' |                        | 01 Oct 2020 18:46:22 |

US3292324

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

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

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.                        | (b) (4)                | 08 Feb 2021 19:49:27 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)       | 01 Oct 2020 18:46:22 |

US3292324

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                | 08 Feb 2021 19:49:27 |
| User entered empty.       | (b) (4), (b) (6)       | 01 Oct 2020 18:46:22 |

US3292324

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)                | 08 Feb 2021 19:49:30 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 01 Oct 2020 18:46:32 |

US3292324

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'l'  | System           | 01 Oct 2020 18:46:32 |

US3292324

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Was Contact Attempted?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:49:51 |
| User entered 'Yes (Y)'    | Kristy Trevino (b) (4) | 08 Oct 2020 15:09:40 |

US3292324

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:49:51 |
| User entered '8 Oct 2020' | Kristy Trevino (b) (4) | 08 Oct 2020 15:09:40 |



US3292324

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

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

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.                        | (b) (4), (b) (6)       | 08 Feb 2021 19:49:51 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) | 08 Oct 2020 15:09:40 |

US3292324

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:49:51 |
| User entered empty.       | Kristy Trevino (b) (4) | 08 Oct 2020 15:09:40 |

US3292324

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:49:55 |
| User entered 'Yes (Y)'    | Kristy Trevino (b) (4) | 08 Oct 2020 15:09:49 |

US3292324

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'l'  | System           | 08 Oct 2020 15:09:49 |

**US3292324**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:34:27**

[Was Contact Attempted?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:50:17 |
| User entered 'Yes (Y)'    | Kristy Trevino (b) (4) | 15 Oct 2020 20:50:16 |

US3292324

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:50:17 |
| User entered '15 Oct 2020' | Kristy Trevino (b) (4) | 15 Oct 2020 20:50:16 |

US3292324

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

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

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.                        | (b) (4), (b) (6)       | 08 Feb 2021 19:50:17 |
| User entered 'Contact Made (CONTACT MADE)' | Kristy Trevino (b) (4) | 15 Oct 2020 20:50:16 |

US3292324

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:50:17 |
| User entered empty.       | Kristy Trevino (b) (4) | 15 Oct 2020 20:50:16 |



US3292324

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:50:23 |
| User entered 'Yes (Y)'    | Kristy Trevino (b) (4) | 15 Oct 2020 20:50:21 |

US3292324

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'l'  | System           | 15 Oct 2020 20:50:21 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:50:40 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 22 Oct 2020 15:40:28 |

**US3292324**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:34:27**

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

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:50:40 |
| User entered '22 Oct 2020' | Gerardo Pena (b) (4)   | 22 Oct 2020 15:40:28 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.      | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.            | (b) (4), (b) (6)       | 08 Feb 2021 19:50:40 |
| User entered 'Clinic (Clinic)' | Gerardo Pena (b) (4)   | 22 Oct 2020 15:40:28 |

**US3292324**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:34:27**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'VISIT3' | System           | 22 Oct 2020 15:40:28 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:51:08 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:13 |

**US3292324**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:34:27**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:51:08 |
| User entered '22 Oct 2020' | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:13 |



US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:51:08 |
| User entered '09:12'      | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered '22 Oct 2020 09:12' | System           | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:51:08 |
| User entered '37.1' C     | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Route of measurement](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:51:08 |
| User entered 'Oral (Oral)' | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:51:08 |
| User entered empty.       | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Pulse \(xxx\)](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 08 Feb 2021 19:51:08 |
| User entered '75'         | Gerardo Pena (b) (4)<br>(b) (4) | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'bpm' | System           | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:51:08 |
| User entered '12'         | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:13 |



US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'breaths/min' | System           | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Systolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:51:08 |
| User entered '123'        | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'mmHg' | System           | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Diastolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:51:08 |
| User entered '75'         | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'mmHg' | System           | 22 Oct 2020 15:41:13 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:34:27

[Was the physical examination performed?](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User closed query 'Please confirm with source, as the " Date Performed" field is entered. ' (Site from CRA). DataPoint Verified.                               |                        | 20 Apr 2021 20:33:45 |
|  |                        | 03 Mar 2021 21:56:44 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
|  | (b) (4)                |                      |
| Query 'Please confirm with source, as the " Date Performed" field is entered. ' answered with 'PE was not conducted data was enter in error ' (Site from CRA). | (b) (4), (b) (6)       | 21 Feb 2021 02:04:32 |
| User opened query 'Please confirm with source, as the " Date Performed" field is entered. ' (Site from CRA).   |                        | 08 Feb 2021 19:52:25 |
| User entered 'No (N)'  | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:26 |
|  | (b) (4)                |                      |



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Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:34:27

Date of examination (dd MMM yyyy)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 25 Apr 2021 12:41:24 |
| DataPoint Verified.       |  | 03 Mar 2021 21:56:44 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered empty.       | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 22 Oct 2020 15:41:26 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:52:43 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:44 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

Collection date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded.  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Feb 2021 19:52:43 |
| User entered '22 Oct 2020' | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:44 |

**US3292324**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:34:27**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:52:43 |
| User entered '09:22'      | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:44 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered '22 Oct 2020 09:22' | System           | 22 Oct 2020 15:41:44 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

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

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 25 Apr 2021 12:41:24 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Feb 2021 19:52:47 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 22 Oct 2020 15:41:48 |

US3292324

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'I'  | System           | 22 Oct 2020 15:41:48 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.    | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 64' | System           | 27 Aug 2020 15:43:21 |



US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-27T07:43:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10ea2bb9-63ac-40fe-b03a-84aa6fd144f2' | System           | 27 Oct 2020 12:43:48 |
| User entered 'No (N)'  | System           | 27 Oct 2020 12:43:48 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-27T07:43:37', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10ea2bb9-63ac-40fe-b03a-84aa6fd144f2' | System           | 27 Oct 2020 12:43:48 |
| User entered 'No (N)'  | System           | 27 Oct 2020 12:43:48 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-10-27T07:43:45', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '10ea2bb9-63ac-40fe-b03a-84aa6fd144f2' User entered '27 Oct 2020 07:43:45' | System           | 27 Oct 2020 12:43:48 |
|  | System           | 27 Oct 2020 12:43:48 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.               | System           | 27 Aug 2020 15:43:21 |
| User entered '27 Oct 2020 00:01' | System           | 27 Aug 2020 15:43:21 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.               | System           | 27 Aug 2020 15:43:21 |
| User entered '31 Oct 2020 23:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.    | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 71' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-04T19:52:50', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd329d5b5-cfa3-4b13-9533-d3dfdc19b57' | System           | 05 Nov 2020 01:53:51 |
| User entered 'Yes (Y)'  | System           | 05 Nov 2020 01:53:51 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-04T19:52:57', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd329d5b5-cfa3-4b13-9533-d3dfdc19b57' | System           | 05 Nov 2020 01:53:51 |
| User entered 'No (N)'   | System           | 05 Nov 2020 01:53:51 |



US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

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) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-04T19:53:02', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd329d5b5-cfa3-4b13-9533-d3dfdc19b57' | System           | 05 Nov 2020 01:53:51 |
| User entered 'No (N)'   | System           | 05 Nov 2020 01:53:51 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

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) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-04T19:53:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd329d5b5-cfa3-4b13-9533-d3dfdc19b57' | System           | 05 Nov 2020 01:53:51 |
| User entered 'Yes (Y)'  | System           | 05 Nov 2020 01:53:51 |

US3292324

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Please 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) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-04T19:53:24', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd329d5b5-cfa3-4b13-9533-d3dfdc19b57' | System           | 05 Nov 2020 01:53:51 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'  | System           | 05 Nov 2020 01:53:51 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-04T19:53:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd329d5b5-cfa3-4b13-9533-d3dfdc19b57' User entered '04 Nov 2020 19:53:42' | System           | 05 Nov 2020 01:53:51 |
|   | System           | 05 Nov 2020 01:53:51 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.               | System           | 27 Aug 2020 15:43:21 |
| User entered '03 Nov 2020 00:01' | System           | 27 Aug 2020 15:43:21 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.               | System           | 27 Aug 2020 15:43:21 |
| User entered '07 Nov 2020 23:59' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.    | System           | 27 Aug 2020 15:43:21 |
| User entered 'Day 78' | System           | 27 Aug 2020 15:43:21 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-11T12:04:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '330cb6e8-32e2-4019-b368-a10d6e9fc698' | System           | 11 Nov 2020 18:05:02 |
| User entered 'Yes (Y)'   | System           | 11 Nov 2020 18:05:02 |



US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-11T12:04:30', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '330cb6e8-32e2-4019-b368-a10d6e9fc698' | System           | 11 Nov 2020 18:05:02 |
| User entered 'No (N)'  | System           | 11 Nov 2020 18:05:02 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

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) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-11T12:04:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '330cb6e8-32e2-4019-b368-a10d6e9fc698' | System           | 11 Nov 2020 18:05:02 |
| User entered 'No (N)'  | System           | 11 Nov 2020 18:05:02 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

[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) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-11T12:04:38', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '330cb6e8-32e2-4019-b368-a10d6e9fc698' | System           | 11 Nov 2020 18:05:02 |
| User entered 'Yes (Y)'   | System           | 11 Nov 2020 18:05:02 |

US3292324

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Please 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) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-11T12:04:45', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '330cb6e8-32e2-4019-b368-a10d6e9fc698' | System           | 11 Nov 2020 18:05:02 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System           | 11 Nov 2020 18:05:02 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-11T12:04:48', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '330cb6e8-32e2-4019-b368-a10d6e9fc698' User entered '11 Nov 2020 12:04:48' | System           | 11 Nov 2020 18:05:02 |
|  | System           | 11 Nov 2020 18:05:02 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.               | System           | 27 Aug 2020 15:43:21 |
| User entered '10 Nov 2020 00:01' | System           | 27 Aug 2020 15:43:21 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:18:10 |
| Data entry locked.               | System           | 27 Aug 2020 15:43:21 |
| User entered '14 Nov 2020 23:59' | System           | 27 Aug 2020 15:43:21 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 18:48:58 |



**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-21T03:28:32', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '88269b42-7908-4c24-922a-e97f989b9cb0' User entered 'No (N)' | System | 21 Nov 2020 09:28:44 |
|  | System | 21 Nov 2020 09:28:44 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-21T03:28:36', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '88269b42-7908-4c24-922a-e97f989b9cb0' User entered 'No (N)' | System | 21 Nov 2020 09:28:44 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-21T03:28:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '88269b42-7908-4c24-922a-e97f989b9cb0' User entered '21 Nov 2020 03:28:42' | System | 21 Nov 2020 09:28:44 |
|  | System | 21 Nov 2020 09:28:44 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-28T00:05:11', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '3a703620-b6b8-4728-8f80-0f59d93f2412' | System | 28 Nov 2020 06:05:42 |
| User entered 'No (N)'  | System | 28 Nov 2020 06:05:42 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-28T00:05:15', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '3a703620-b6b8-4728-8f80-0f59d93f2412' | System | 28 Nov 2020 06:05:42 |
| User entered 'No (N)'  | System | 28 Nov 2020 06:05:42 |



**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-11-28T00:05:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '3a703620-b6b8-4728-8f80-0f59d93f2412' User entered '28 Nov 2020 00:05:25' | System | 28 Nov 2020 06:05:42 |
|  | System | 28 Nov 2020 06:05:42 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-12-05T08:13:59', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0c0ee5ea-c343-48cf-8648-371dd68a5a70' | System | 05 Dec 2020 14:14:22 |
| User entered 'No (N)'  | System | 05 Dec 2020 14:14:22 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-12-05T08:14:08', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0c0ee5ea-c343-48cf-8648-371dd68a5a70' | System | 05 Dec 2020 14:14:22 |
| User entered 'No (N)'  | System | 05 Dec 2020 14:14:22 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-12-05T08:14:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0c0ee5ea-c343-48cf-8648-371dd68a5a70' User entered '05 Dec 2020 08:14:19' | System | 05 Dec 2020 14:14:22 |
|  | System | 05 Dec 2020 14:14:22 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System | 19 Nov 2020 18:48:58 |



**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-12-12T03:03:30', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '3d8337b5-a7a0-47ae-9d68-f90209da2cad' User entered 'No (N)' | System | 12 Dec 2020 09:03:42 |
|  | System | 12 Dec 2020 09:03:42 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-12-12T03:03:34', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '3d8337b5-a7a0-47ae-9d68-f90209da2cad' User entered 'No (N)' | System | 12 Dec 2020 09:03:42 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-12-12T03:03:38', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '3d8337b5-a7a0-47ae-9d68-f90209da2cad' User entered '12 Dec 2020 03:03:38' | System | 12 Dec 2020 09:03:42 |
|  | System | 12 Dec 2020 09:03:42 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 18:48:58 |



**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-12-19T07:19:23', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ad1dfe58-923b-49f2-bc51-3ecc678228c6' User entered 'No (N)' | System | 19 Dec 2020 13:19:40 |
|  | System | 19 Dec 2020 13:19:40 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-12-19T07:19:27', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ad1dfe58-923b-49f2-bc51-3ecc678228c6' User entered 'No (N)' | System | 19 Dec 2020 13:19:40 |
|  | System | 19 Dec 2020 13:19:40 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-12-19T07:19:34', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ad1dfe58-923b-49f2-bc51-3ecc678228c6' User entered '19 Dec 2020 07:19:34' | System | 19 Dec 2020 13:19:40 |
|  | System | 19 Dec 2020 13:19:40 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-12-26T04:56:52', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ec045316-8cf2-49a5-b9ff-be9f7df614f7' | System | 26 Dec 2020 10:57:02 |
| User entered 'No (N)'  | System | 26 Dec 2020 10:57:02 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-12-26T04:56:56', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ec045316-8cf2-49a5-b9ff-be9f7df614f7' | System | 26 Dec 2020 10:57:02 |
| User entered 'No (N)'  | System | 26 Dec 2020 10:57:02 |



**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2020-12-26T04:56:59', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ec045316-8cf2-49a5-b9ff-be9f7df614f7' User entered '26 Dec 2020 04:56:59' | System | 26 Dec 2020 10:57:02 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-02T10:57:13', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '76d7df04-fff5-4292-8b6d-777aefca2184' User entered 'No (N)' | System | 02 Jan 2021 16:57:23 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-02T10:57:16', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '76d7df04-fff5-4292-8b6d-777aefca2184' | System | 02 Jan 2021 16:57:23 |
| User entered 'No (N)'  | System | 02 Jan 2021 16:57:23 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-02T10:57:20', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '76d7df04-fff5-4292-8b6d-777aefca2184' User entered '02 Jan 2021 10:57:20' | System | 02 Jan 2021 16:57:23 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Jan 2021 00:01' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Jan 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-09T00:40:30', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b04cacc1-b4bb-41e2-965d-7f3290b33b1b' User entered 'No (N)' | System | 09 Jan 2021 06:40:54 |
|  | System | 09 Jan 2021 06:40:54 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-09T00:40:39', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b04cacc1-b4bb-41e2-965d-7f3290b33b1b' User entered 'No (N)' | System | 09 Jan 2021 06:40:54 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-09T00:40:51', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b04cacc1-b4bb-41e2-965d-7f3290b33b1b' User entered '09 Jan 2021 00:40:51' | System | 09 Jan 2021 06:40:54 |
|  | System | 09 Jan 2021 06:40:54 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Jan 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Jan 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-16T05:44:28', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd9026693-7375-4cf1-b7c0-e548d607169a' User entered 'No (N)' | System | 16 Jan 2021 11:44:42 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-16T05:44:33', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd9026693-7375-4cf1-b7c0-e548d607169a' User entered 'No (N)' | System | 16 Jan 2021 11:44:42 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-16T05:44:39', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'd9026693-7375-4cf1-b7c0-e548d607169a' User entered '16 Jan 2021 05:44:39' | System | 16 Jan 2021 11:44:42 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Jan 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Jan 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-23T00:01:36', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ebec76c7-5da0-44ed-9130-4271e99f4796' | System | 23 Jan 2021 06:02:14 |
| User entered 'No (N)'  | System | 23 Jan 2021 06:02:14 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-23T00:01:41', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ebec76c7-5da0-44ed-9130-4271e99f4796' | System | 23 Jan 2021 06:02:14 |
| User entered 'No (N)'  | System | 23 Jan 2021 06:02:14 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-23T00:01:47', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ebec76c7-5da0-44ed-9130-4271e99f4796' User entered '23 Jan 2021 00:01:47' | System | 23 Jan 2021 06:02:14 |
|  | System | 23 Jan 2021 06:02:14 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Jan 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Jan 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-31T07:14:02', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fc521379-5522-446e-a092-9d0d45859b7b' User entered 'No (N)' | System | 31 Jan 2021 13:14:16 |
|  | System | 31 Jan 2021 13:14:16 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-31T07:14:07', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fc521379-5522-446e-a092-9d0d45859b7b' User entered 'No (N)' | System | 31 Jan 2021 13:14:16 |
|  | System | 31 Jan 2021 13:14:16 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-01-31T07:14:12', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'fc521379-5522-446e-a092-9d0d45859b7b' User entered '31 Jan 2021 07:14:12' | System | 31 Jan 2021 13:14:16 |
|  | System | 31 Jan 2021 13:14:16 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Jan 2021 00:01' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Feb 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-06T04:43:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0153376c-b6fb-4054-9441-f278c78796c1' User entered 'No (N)' | System | 06 Feb 2021 10:43:52 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-06T04:43:43', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0153376c-b6fb-4054-9441-f278c78796c1' User entered 'No (N)' | System | 06 Feb 2021 10:43:52 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-06T04:43:49', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '0153376c-b6fb-4054-9441-f278c78796c1' User entered '06 Feb 2021 04:43:49' | System | 06 Feb 2021 10:43:52 |
|  | System | 06 Feb 2021 10:43:52 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Feb 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Feb 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-13T09:38:19', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'cb84bc41-e8cf-4ca9-8cbd-f45482775de2' User entered 'No (N)' | System | 13 Feb 2021 15:38:28 |
|  | System | 13 Feb 2021 15:38:28 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-13T09:38:22', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'cb84bc41-e8cf-4ca9-8cbd-f45482775de2' User entered 'No (N)' | System | 13 Feb 2021 15:38:28 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-13T09:38:25', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'cb84bc41-e8cf-4ca9-8cbd-f45482775de2' | System | 13 Feb 2021 15:38:28 |
| User entered '13 Feb 2021 09:38:25'  | System | 13 Feb 2021 15:38:28 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Feb 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Feb 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-20T01:34:31', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '226faf55-584f-4334-b0fa-77ae76dcc56e' User entered 'No (N)' | System | 20 Feb 2021 07:35:05 |
|  | System | 20 Feb 2021 07:35:05 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-20T01:34:35', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '226faf55-584f-4334-b0fa-77ae76dcc56e' User entered 'No (N)' | System | 20 Feb 2021 07:35:05 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-20T01:34:42', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '226faf55-584f-4334-b0fa-77ae76dcc56e' User entered '20 Feb 2021 01:34:42' | System | 20 Feb 2021 07:35:05 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Feb 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Feb 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-27T17:30:04-06:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ce33d83d-eda7-4665-92a8-4869792d4f37' User entered 'No (N)' | System | 27 Feb 2021 23:30:12 |
|  | System | 27 Feb 2021 23:30:12 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-27T17:30:07-06:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ce33d83d-eda7-4665-92a8-4869792d4f37' User entered 'No (N)' | System | 27 Feb 2021 23:30:12 |
|  | System | 27 Feb 2021 23:30:12 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-27T17:30:10-06:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ce33d83d-eda7-4665-92a8-4869792d4f37' | System | 27 Feb 2021 23:30:12 |
| User entered '27 Feb 2021 23:30:10'  | System | 27 Feb 2021 23:30:12 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Feb 2021 00:01' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Mar 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-03-06T07:15:28-06:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4ca6af5-0081-4913-9380-d3c1b68e2d69' User entered 'No (N)' | System | 06 Mar 2021 13:15:39 |
|  | System | 06 Mar 2021 13:15:39 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-03-06T07:15:33-06:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4ca6af5-0081-4913-9380-d3c1b68e2d69' | System | 06 Mar 2021 13:15:39 |
| User entered 'No (N)'  | System | 06 Mar 2021 13:15:39 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-03-06T07:15:36-06:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'e4ca6af5-0081-4913-9380-d3c1b68e2d69' User entered '06 Mar 2021 07:15:36' | System | 06 Mar 2021 13:15:39 |
|  | System | 06 Mar 2021 13:15:39 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Mar 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Mar 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 18:48:58 |



US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-03-13T06:02:35-06:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6465f18-9455-4e11-b37d-bcff5253786b' User entered 'No (N)' | System | 13 Mar 2021 12:02:48 |
|  | System | 13 Mar 2021 12:02:48 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-03-13T06:02:40-06:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6465f18-9455-4e11-b37d-bcff5253786b' User entered 'No (N)' | System | 13 Mar 2021 12:02:48 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-03-13T06:02:45-06:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'b6465f18-9455-4e11-b37d-bcff5253786b' User entered '13 Mar 2021 06:02:45' | System | 13 Mar 2021 12:02:48 |
|  | System | 13 Mar 2021 12:02:48 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Mar 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Mar 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-03-23T03:52:09-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '25a75589-7b0a-47d9-817f-f4ef05a200ed' | System | 23 Mar 2021 08:52:21 |
| User entered 'No (N)'  | System | 23 Mar 2021 08:52:21 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-03-23T03:52:13-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '25a75589-7b0a-47d9-817f-f4ef05a200ed' | System | 23 Mar 2021 08:52:21 |
| User entered 'No (N)'  | System | 23 Mar 2021 08:52:21 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-03-23T03:52:17-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '25a75589-7b0a-47d9-817f-f4ef05a200ed' User entered '23 Mar 2021 03:52:17' | System | 23 Mar 2021 08:52:21 |
|  | System | 23 Mar 2021 08:52:21 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Mar 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Mar 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-03-27T23:17:32-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '4e0b8503-0886-4b84-9c20-c0051369c722' | System | 28 Mar 2021 04:17:45 |
| User entered 'No (N)'  | System | 28 Mar 2021 04:17:45 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-03-27T23:17:35-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '4e0b8503-0886-4b84-9c20-c0051369c722' | System | 28 Mar 2021 04:17:45 |
| User entered 'No (N)'  | System | 28 Mar 2021 04:17:45 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-03-27T23:17:40-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '4e0b8503-0886-4b84-9c20-c0051369c722' | System | 28 Mar 2021 04:17:45 |
| User entered '27 Mar 2021 23:17:40'  | System | 28 Mar 2021 04:17:45 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Mar 2021 00:01' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '31 Mar 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-04-03T00:24:46-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'bd6365e8-f486-41fd-a561-c5b326b8adf4' User entered 'No (N)' | System | 03 Apr 2021 05:24:58 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-04-03T00:24:49-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'bd6365e8-f486-41fd-a561-c5b326b8adf4' User entered 'No (N)' | System | 03 Apr 2021 05:24:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-04-03T00:24:54-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'bd6365e8-f486-41fd-a561-c5b326b8adf4' | System | 03 Apr 2021 05:24:58 |
| User entered '03 Apr 2021 00:24:54'  | System | 03 Apr 2021 05:24:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Apr 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '07 Apr 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-04-11T19:02:24-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'bd511fca-0951-45f1-bf61-cf815ba3bf6e' User entered 'No (N)' | System | 12 Apr 2021 00:02:41 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-04-11T19:02:30-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'bd511fca-0951-45f1-bf61-cf815ba3bf6e' User entered 'No (N)' | System | 12 Apr 2021 00:02:41 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-04-11T19:02:35-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'bd511fca-0951-45f1-bf61-cf815ba3bf6e' User entered '11 Apr 2021 19:02:35' | System | 12 Apr 2021 00:02:41 |
|  | System | 12 Apr 2021 00:02:41 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Apr 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '14 Apr 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-04-17T04:43:29-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'bc62c0f8-7061-4aaa-88c9-cd3163a8fcf7' | System | 17 Apr 2021 09:43:43 |
| User entered 'No (N)'  | System | 17 Apr 2021 09:43:43 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-04-17T04:43:34-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'bc62c0f8-7061-4aaa-88c9-cd3163a8fcf7' | System | 17 Apr 2021 09:43:43 |
| User entered 'No (N)'  | System | 17 Apr 2021 09:43:43 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-04-17T04:43:40-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'bc62c0f8-7061-4aaa-88c9-cd3163a8fcf7' | System | 17 Apr 2021 09:43:43 |
| User entered '17 Apr 2021 04:43:40'  | System | 17 Apr 2021 09:43:43 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Apr 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '21 Apr 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-04-24T07:10:46-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ebb927b7-ab7c-48cc-bde2-35a9473c328a' User entered 'No (N)' | System | 24 Apr 2021 12:49:37 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-04-24T07:10:51-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ebb927b7-ab7c-48cc-bde2-35a9473c328a' User entered 'No (N)' | System | 24 Apr 2021 12:49:37 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-04-24T07:10:55-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: 'ebb927b7-ab7c-48cc-bde2-35a9473c328a' User entered '24 Apr 2021 07:10:55' | System | 24 Apr 2021 12:49:37 |
|  | System | 24 Apr 2021 12:49:37 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Apr 2021 00:01' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '28 Apr 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-05-01T07:48:03-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6d3c17ee-ffdf-4de3-a42f-fc3b49881b44' | System | 01 May 2021 12:48:12 |
| User entered 'No (N)'  | System | 01 May 2021 12:48:12 |

US3292324

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:34:27

Have you been exposed to someone with 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 (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-05-01T07:48:06-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6d3c17ee-ffdf-4de3-a42f-fc3b49881b44' | System | 01 May 2021 12:48:12 |
| User entered 'No (N)'  | System | 01 May 2021 12:48:12 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-05-01T07:48:09-05:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '6d3c17ee-ffdf-4de3-a42f-fc3b49881b44' | System | 01 May 2021 12:48:12 |
| User entered '01 May 2021 07:48:09'  | System | 01 May 2021 12:48:12 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '01 May 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 May 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '08 May 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 May 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '15 May 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '19 May 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '22 May 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '26 May 2021 23:59' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '29 May 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Jun 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 Jun 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Jun 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 Jun 2021 00:01' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Jun 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '19 Jun 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Jun 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '26 Jun 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Jun 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 18:48:58 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Jul 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '07 Jul 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Jul 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '14 Jul 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Jul 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '21 Jul 2021 23:59' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Jul 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '28 Jul 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '31 Jul 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '04 Aug 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '07 Aug 2021 00:01' | System | 19 Nov 2020 18:48:58 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '11 Aug 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '14 Aug 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '18 Aug 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '21 Aug 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '25 Aug 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '28 Aug 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '01 Sep 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '04 Sep 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '08 Sep 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '11 Sep 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '15 Sep 2021 23:59' | System | 19 Nov 2020 18:48:58 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '18 Sep 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '22 Sep 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '25 Sep 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '29 Sep 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Oct 2021 00:01' | System | 19 Nov 2020 18:48:58 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Oct 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Oct 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Oct 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Oct 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Oct 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Oct 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Oct 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Oct 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Nov 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Nov 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Nov 2021 23:59' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Nov 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Nov 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Nov 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Nov 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Nov 2021 00:01' | System | 19 Nov 2020 18:48:58 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '01 Dec 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '04 Dec 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '08 Dec 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '11 Dec 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '15 Dec 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 18:48:58 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '18 Dec 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '22 Dec 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '25 Dec 2021 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '29 Dec 2021 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '01 Jan 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 Jan 2022 23:59' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '08 Jan 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 Jan 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '15 Jan 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**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 18:48:58 |
| Amendment Manager: User entered '19 Jan 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '22 Jan 2022 00:01' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**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 18:48:58 |
| Amendment Manager: User entered '26 Jan 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '29 Jan 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:34:27**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Feb 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 Feb 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Feb 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 Feb 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Feb 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '19 Feb 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Feb 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '26 Feb 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Mar 2022 23:59' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 Mar 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Mar 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 Mar 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Mar 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '19 Mar 2022 00:01' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Mar 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '26 Mar 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Mar 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Apr 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Apr 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 18:48:58 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Apr 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Apr 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Apr 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Apr 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Apr 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Apr 2022 23:59' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Apr 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '04 May 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '07 May 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '11 May 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '14 May 2022 00:01' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '18 May 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '21 May 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '25 May 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '28 May 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '01 Jun 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 18:48:58 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '04 Jun 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '08 Jun 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '11 Jun 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**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 18:48:58 |
| Amendment Manager: User entered '15 Jun 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '18 Jun 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '22 Jun 2022 23:59' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '25 Jun 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '29 Jun 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Jul 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Jul 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '09 Jul 2022 00:01' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Jul 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '16 Jul 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Jul 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '23 Jul 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Jul 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '30 Jul 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Aug 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '06 Aug 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Aug 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '13 Aug 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Aug 2022 23:59' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '20 Aug 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Aug 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '27 Aug 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '31 Aug 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '03 Sep 2022 00:01' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '07 Sep 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '10 Sep 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '14 Sep 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '17 Sep 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '21 Sep 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '24 Sep 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '28 Sep 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '01 Oct 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '05 Oct 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '08 Oct 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '12 Oct 2022 23:59' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '15 Oct 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '19 Oct 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '22 Oct 2022 00:01' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '26 Oct 2022 23:59' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 18:48:58 |

**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '29 Oct 2022 00:01' | System | 19 Nov 2020 18:48:58 |



**US3292324**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:34:27**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 18:48:58 |
| Amendment Manager: User entered '02 Nov 2022 23:59' | System | 19 Nov 2020 18:48:58 |

US3292324

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:34:27**

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 23:11:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-27T17:30:24-06:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '3108bff7-d751-4429-9659-0f85506b2862' | System           | 27 Feb 2021 23:30:36 |
| User entered 'No (N)'  | System           | 27 Feb 2021 23:30:36 |

**US3292324**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Date & Time of Submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 23:11:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7ED5F20-4B8A-4DE5-AEED-8F09620CB7E8)', Time: '2021-02-27T17:30:32-06:00', User OID: 'PatientReportedOutcome (US3292324)', ODM File OID: '3108bff7-d751-4429-9659-0f85506b2862' | System           | 27 Feb 2021 23:30:36 |
| User entered '27 Feb 2021 23:30:32'  | System           | 27 Feb 2021 23:30:36 |

US3292324

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Was Contact Attempted?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 25 Apr 2021 12:41:24 |
| DataPoint Verified.       |  | 03 Mar 2021 22:13:00 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Nov 2020 19:29:09 |

US3292324

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 25 Apr 2021 12:41:24 |
| DataPoint Verified.        |  | 03 Mar 2021 22:13:00 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered '19 Nov 2020' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Nov 2020 19:29:09 |

US3292324

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                           | 25 Apr 2021 12:41:24 |
| DataPoint Verified.                        |  | 03 Mar 2021 22:13:00 |
| User signature succeeded.                  | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Nov 2020 19:29:09 |

US3292324

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 25 Apr 2021 12:41:24 |
| DataPoint Verified.       |  | 03 Mar 2021 22:13:00 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered empty.       | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Nov 2020 19:29:09 |

US3292324

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 25 Apr 2021 12:41:24 |
| DataPoint Verified.       |  | 03 Mar 2021 22:13:39 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Nov 2020 19:29:13 |



US3292324

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 12:41:24 |
| User entered 'l'  | System           | 23 Nov 2020 19:29:13 |

US3292324

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Was Contact Attempted?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 15 Apr 2021 04:57:22 |
| DataPoint Verified.       |  | 03 Mar 2021 22:14:00 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Dec 2020 19:57:07 |

US3292324

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 15 Apr 2021 04:57:22 |
| DataPoint Verified.        |  | 03 Mar 2021 22:14:00 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered '22 Dec 2020' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Dec 2020 19:57:07 |

US3292324

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                           | 15 Apr 2021 04:57:22 |
| DataPoint Verified.                        |  | 03 Mar 2021 22:14:00 |
| User signature succeeded.                  | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Dec 2020 19:57:07 |

US3292324

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 15 Apr 2021 04:57:22 |
| DataPoint Verified.       |  | 03 Mar 2021 22:14:00 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered empty.       | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Dec 2020 19:57:07 |

US3292324

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 15 Apr 2021 04:57:22 |
| DataPoint Verified.       |  | 03 Mar 2021 22:14:49 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Dec 2020 19:58:36 |

**US3292324**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:34:27**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:57:22 |
| User entered 'l'  | System           | 23 Dec 2020 19:58:36 |

US3292324

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 15 Apr 2021 04:57:22 |
| DataPoint Verified.       |                             | 03 Mar 2021 22:16:03 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 14:48:01 |



US3292324

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 15 Apr 2021 04:57:22 |
| DataPoint Verified.        |                             | 03 Mar 2021 22:16:03 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered '23 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 14:48:01 |

US3292324

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Please select one status for the follow-up contact](#)

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 15 Apr 2021 04:57:22 |
| DataPoint Verified.                        | (b) (4)                | 03 Mar 2021 22:16:03 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6)       | 27 Jan 2021 14:48:01 |

US3292324

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 15 Apr 2021 04:57:22 |
| DataPoint Verified.       |                             | 03 Mar 2021 22:16:03 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 14:48:01 |

US3292324

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 15 Apr 2021 04:57:22 |
| DataPoint Verified.       |                             | 03 Mar 2021 22:16:30 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 14:48:08 |

**US3292324**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:34:27**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:57:22 |
| User entered 'l'  | System           | 27 Jan 2021 14:48:08 |

US3292324

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Was Contact Attempted?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 15 Apr 2021 04:57:22 |
| DataPoint Verified.       |  | 03 Mar 2021 22:17:11 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 23 Feb 2021 18:42:47 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Feb 2021 16:29:03 |

US3292324

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit                      | User                                       | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                           | 15 Apr 2021 04:57:22 |
| DataPoint Verified.        |  | 03 Mar 2021 22:17:11 |
| User signature succeeded.  | Douglas Denham (b) (4)                     | 23 Feb 2021 18:42:47 |
| User entered '22 Feb 2021' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Feb 2021 16:29:03 |

US3292324

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                           | 15 Apr 2021 04:57:22 |
| DataPoint Verified.                        |  | 03 Mar 2021 22:17:11 |
| User signature succeeded.                  | Douglas Denham (b) (4)                     | 23 Feb 2021 18:42:47 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Feb 2021 16:29:03 |



US3292324

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:34:27

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 15 Apr 2021 04:57:22 |
| DataPoint Verified.       |  | 03 Mar 2021 22:17:11 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 23 Feb 2021 18:42:47 |
| User entered empty.       | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Feb 2021 16:29:03 |

US3292324

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 15 Apr 2021 04:57:22 |
| DataPoint Verified.       |  | 03 Mar 2021 22:17:54 |
| User signature succeeded. | Douglas Denham (b) (4)                     | 23 Feb 2021 18:42:47 |
| User entered 'Yes (Y)'    | (b) (4)<br>Gerardo Pena (b) (4)<br>(b) (4) | 23 Feb 2021 16:29:08 |

**US3292324**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:34:27**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 15 Apr 2021 04:57:22 |
| User entered 'l'  | System           | 23 Feb 2021 16:29:08 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Apr 2021 16:45:08 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 25 Mar 2021 15:35:04 |

**US3292324**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:34:27**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Apr 2021 16:45:08 |
| User entered '23 Mar 2021' | Gerardo Pena (b) (4)   | 25 Mar 2021 15:35:04 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[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 18:23:09 |
| User signature succeeded.      | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.            | (b) (4), (b) (6)       | 08 Apr 2021 16:45:08 |
| User entered 'Clinic (Clinic)' | Gerardo Pena (b) (4)   | 25 Mar 2021 15:35:04 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'VISIT4' | System           | 25 Mar 2021 15:35:04 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:45:13 |
| User entered 'No (N)'     |                             | 31 Mar 2021 19:23:01 |



US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:45:13 |
| User entered empty.       |                             | 31 Mar 2021 19:23:01 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Time of assessment (00:00-23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Apr 2021 16:45:13 |
| User entered empty.       |                        | 31 Mar 2021 19:23:01 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 31 Mar 2021 19:23:01 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Apr 2021 16:45:13 |
| User entered empty.       |                        | 31 Mar 2021 19:23:01 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Route of measurement](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Apr 2021 16:45:13 |
| User entered empty.       |                        | 31 Mar 2021 19:23:01 |

**US3292324**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:34:27**

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4)                | 08 Apr 2021 16:45:13 |
| User entered empty.       | (b) (4), (b) (6)       | 31 Mar 2021 19:23:01 |

**US3292324**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:34:27**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:45:13 |
| User entered empty.       |                             | 31 Mar 2021 19:23:01 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 31 Mar 2021 19:23:01 |



US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:45:13 |
| User entered empty.       |                             | 31 Mar 2021 19:23:01 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Respiratory Rate units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 31 Mar 2021 19:23:01 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Systolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Apr 2021 16:45:13 |
| User entered empty.       |                        | 31 Mar 2021 19:23:01 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 31 Mar 2021 19:23:01 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Diastolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:45:13 |
| User entered empty.       |                             | 31 Mar 2021 19:23:01 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered empty. | System           | 31 Mar 2021 19:23:01 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:34:27

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |



US3292324

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:34:27

[Was the physical examination performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Apr 2021 16:45:20 |
| User entered 'No (N)'     | Gerardo Pena (b) (4)   | 25 Mar 2021 15:35:14 |

**US3292324**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:34:27**

**Date of examination (dd MMM yyyy)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Apr 2021 16:45:20 |
| User entered empty.       | Gerardo Pena (b) (4)   | 25 Mar 2021 15:35:14 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Apr 2021 16:45:27 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 25 Mar 2021 15:35:27 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

Collection date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded.  | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 08 Apr 2021 16:45:27 |
| User entered '23 Mar 2021' | Gerardo Pena (b) (4)   | 25 Mar 2021 15:35:27 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

Collection time (00:00-23:59)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Apr 2021 16:45:27 |
| User entered '09:45'      | Gerardo Pena (b) (4)   | 25 Mar 2021 15:35:27 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered '23 Mar 2021 09:45' | System           | 25 Mar 2021 15:35:27 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 28 Apr 2021 18:23:09 |
| User signature succeeded. | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 08 Apr 2021 16:45:39 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 25 Mar 2021 15:35:32 |

US3292324

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:34:27

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:23:09 |
| User entered 'I'  | System           | 25 Mar 2021 15:35:32 |



US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[Was this visit performed?](#)

| Audit                     | User                                  | Time (GMT)           |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                      | 28 Apr 2021 20:38:26 |
| DataPoint Verified.       |                                       | 03 Mar 2021 22:18:59 |
| User signature succeeded. | Douglas Denham (b) (4)                | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 21:22:47 |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                                  | Time (GMT)           |
|----------------------------|---------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                      | 28 Apr 2021 20:38:26 |
| DataPoint Verified.        |                                       | 03 Mar 2021 22:18:59 |
| User signature succeeded.  | Douglas Denham (b) (4)                | 23 Feb 2021 14:15:51 |
| User entered '14 Jan 2021' | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 21:22:47 |
|                            | (b) (4)                               |                      |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[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 20:38:26 |
| DataPoint Verified.            |                                       | 03 Mar 2021 22:18:59 |
| User signature succeeded.      | Douglas Denham (b) (4)                | 23 Feb 2021 14:15:51 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 21:22:47 |
|                                | (b) (4)                               |                      |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:34:27

[Folder OID](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 20:38:26 |
| User entered 'UNBLND_DECIDE' | System           | 18 Jan 2021 21:22:47 |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:34:27

Date of updated informed consent (*dd MMM yyyy*)

| Audit                      | User                                  | Time (GMT)           |
|----------------------------|---------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                      | 28 Apr 2021 20:38:26 |
| DataPoint Verified.        | (b) (4), (b) (6)                      | 12 Apr 2021 17:21:21 |
| User signature succeeded.  | Douglas Denham (b) (4)                | 23 Feb 2021 14:15:51 |
| User entered '14 Jan 2021' | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 21:23:23 |

**US3292324**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:34:27**

[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 20:38:26 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| User entered '0' WR# 5295537               | (b) (4)                | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System                 | 06 Mar 2021 07:03:40 |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:34:27

[Was the participant unblinded?](#)

| Audit                     | User                                  | Time (GMT)           |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                      | 28 Apr 2021 20:38:26 |
| DataPoint Verified.       |                                       | 12 Apr 2021 17:21:21 |
| User signature succeeded. | Douglas Denham (b) (4)                | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 21:23:23 |
|                           | (b) (4)                               |                      |

**US3292324**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:34:27**

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 20:38:26 |
| User signature succeeded.   | Douglas Denham (b) (4) | 16 Apr 2021 14:42:31 |
| 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 07:03:40 |



US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:34:27

Date of unblinding (*dd MMM yyyy*)

| Audit                      | User                                  | Time (GMT)           |
|----------------------------|---------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                      | 28 Apr 2021 20:38:26 |
| DataPoint Verified.        |                                       | 12 Apr 2021 17:21:21 |
| User signature succeeded.  | Douglas Denham (b) (4)                | 23 Feb 2021 14:15:51 |
| User entered '14 Jan 2021' | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 21:23:23 |
|                            | (b) (4)                               |                      |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:34:27

[Participant randomization assignment](#)

| Audit                                | User                                  | Time (GMT)           |
|--------------------------------------|---------------------------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)                      | 28 Apr 2021 20:38:26 |
| DataPoint Verified.                  | (b) (4)                               | 12 Apr 2021 17:21:21 |
| User signature succeeded.            | Douglas Denham (b) (4)                | 23 Feb 2021 14:15:51 |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 21:23:23 |
|                                      | (b) (4)                               |                      |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:34:27

[Actual Dose 1](#)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.                                       | (b) (4), (b) (6)           | 28 Apr 2021 20:38:26 |
| DataPoint Verified.                                     |                            | 12 Apr 2021 17:21:21 |
| User signature succeeded.                               | Douglas Denham (b) (4)     | 23 Feb 2021 14:15:51 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | (b) (4)<br>System          | 20 Jan 2021 03:28:51 |
| User entered 'mRNA-1273 (mRNA-1273)'                    | Victoria Hernandez (b) (4) | 18 Jan 2021 21:23:23 |
|   | (b) (4)                    |                      |

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:34:27

[Actual Dose 2](#)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.                                       | (b) (4), (b) (6)           | 28 Apr 2021 20:38:26 |
| DataPoint Verified.                                     | (b) (4)                    | 12 Apr 2021 17:21:21 |
| User signature succeeded.                               | Douglas Denham (b) (4)     | 23 Feb 2021 14:15:51 |
| Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)' | (b) (4)                    | 20 Jan 2021 03:28:51 |
| User entered 'mRNA-1273 (mRNA-1273)'                    | Victoria Hernandez (b) (4) | 18 Jan 2021 21:23:23 |
|   | (b) (4)                    |                      |

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:34:27

[Will participant receive mRNA-1273?](#)

| Audit                     | User                                  | Time (GMT)           |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                      | 28 Apr 2021 20:38:26 |
| DataPoint Verified.       |                                       | 12 Apr 2021 17:21:21 |
| User signature succeeded. | Douglas Denham (b) (4)                | 23 Feb 2021 14:15:51 |
| User entered 'No (N)'     | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 21:23:23 |
|                           | (b) (4)                               |                      |

**US3292324**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:34:27**

[Placebo Only Flag](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 20:38:26 |
| User entered empty. | System           | 18 Jan 2021 21:23:23 |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:34:27

[Continuing with mRNA-1273](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 20:38:26 |
| User entered empty. | System           | 18 Jan 2021 21:23:23 |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

[Was the sample collected?](#)

| Audit                     | User                                  | Time (GMT)           |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                      | 28 Apr 2021 20:38:26 |
| DataPoint Verified.       |                                       | 03 Mar 2021 22:19:39 |
| User signature succeeded. | Douglas Denham (b) (4)                | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 21:23:40 |



US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

Collection date (dd MMM yyyy)

| Audit                      | User                                  | Time (GMT)           |
|----------------------------|---------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                      | 28 Apr 2021 20:38:26 |
| DataPoint Verified.        | (b) (4), (b) (6)                      | 03 Mar 2021 22:19:39 |
| User signature succeeded.  | Douglas Denham (b) (4)                | 23 Feb 2021 14:15:51 |
| User entered '14 Jan 2021' | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 21:23:40 |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

Collection time (00:00-23:59)

| Audit                     | User                                  | Time (GMT)           |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                      | 28 Apr 2021 20:38:26 |
| DataPoint Verified.       |                                       | 03 Mar 2021 22:19:39 |
| User signature succeeded. | Douglas Denham (b) (4)                | 23 Feb 2021 14:15:51 |
| User entered '10:15'      | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 21:23:40 |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:34:27

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 20:38:26 |
| User entered '14 Jan 2021 10:15' | System           | 18 Jan 2021 21:23:40 |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:34:27

[Was the sample collected?](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)           | 28 Apr 2021 20:38:26 |
| DataPoint Verified.  | (b) (4), (b) (6)           | 12 Apr 2021 17:21:38 |
| User closed query 'Question is blank in source. Please provide an answer' (Site from CRA).             | (b) (4), (b) (6)           | 12 Apr 2021 17:21:35 |
| Query 'Question is blank in source. Please provide an answer' answered with 'updated' (Site from CRA). | Victoria Hernandez (b) (4) | 24 Mar 2021 16:24:16 |
| User opened query 'Question is blank in source. Please provide an answer' (Site from CRA).             | (b) (4)                    |                      |
| DataPoint Un-verified.   | (b) (4), (b) (6)           | 03 Mar 2021 22:20:34 |
|  | (b) (4), (b) (6)           | 03 Mar 2021 22:20:01 |
| DataPoint Verified.  | (b) (4), (b) (6)           | 03 Mar 2021 22:19:47 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 23 Feb 2021 14:15:51 |
| User entered 'Yes (Y)'   | (b) (4)                    |                      |
|  | Victoria Hernandez (b) (4) | 18 Jan 2021 21:23:52 |
|  | (b) (4)                    |                      |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:34:27

Collection date (dd MMM yyyy)

| Audit                      | User                                  | Time (GMT)           |
|----------------------------|---------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                      | 28 Apr 2021 20:38:26 |
| DataPoint Verified.        |                                       | 03 Mar 2021 22:19:47 |
| User signature succeeded.  | Douglas Denham (b) (4)                | 23 Feb 2021 14:15:51 |
| User entered '14 Jan 2021' | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 21:23:52 |
|                            | (b) (4)                               |                      |

US3292324

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:34:27

Collection time (00:00 - 23:59)

| Audit                     | User                                  | Time (GMT)           |
|---------------------------|---------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                      | 28 Apr 2021 20:38:26 |
| DataPoint Verified.       |                                       | 03 Mar 2021 22:19:47 |
| User signature succeeded. | Douglas Denham (b) (4)                | 23 Feb 2021 14:15:51 |
| User entered '10:20'      | (b) (4)<br>Victoria Hernandez (b) (4) | 18 Jan 2021 21:23:52 |

**US3292324**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:34:27**

[Collection Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 20:38:26 |
| User entered '14 Jan 2021 10:20' | System           | 18 Jan 2021 21:23:52 |

US3292324

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:34:27

[Did the participant experience any adverse events?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 03 May 2021 05:13:34 |
| DataPoint Verified.       | (b) (4), (b) (6)                             | 03 Mar 2021 21:57:40 |
| User signature succeeded. | Douglas Denham (b) (4)                       | 23 Feb 2021 14:15:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>Kevin Martinez (b) (4)<br>(b) (4) | 24 Sep 2020 17:15:28 |



**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:55:32 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

[Adverse event](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 23 Nov 2020 17:52:01 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0. | Coder Import (b) (4)   | 24 Sep 2020 17:17:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)   | 24 Sep 2020 17:17:54 |
| Data point term sent to Coder  | System                 | 24 Sep 2020 17:17:09 |
| User entered 'urinary tract infection'   | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Was this a medically-attended AE?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:02 |
| User entered 'No (N)'     | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:03 |
| User entered 'No (N)'     | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:06 |
| User entered 'No (N)'     | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 23 Nov 2020 17:52:08 |
| User entered '16 Sep 2020' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:09 |
| User entered empty.       | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 11:55:32 |
| User entered empty. | System           | 24 Sep 2020 17:17:08 |



US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

[Ongoing?](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded.                                 | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                                       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:11 |
| User entered 'No (N)' reason for change: Data Entry Error | Dawn Killian (b) (4)   | 04 Nov 2020 19:03:51 |
| User entered 'Yes (Y)'                                    | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

If not Ongoing, end date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 23 Nov 2020 17:52:12 |
| User entered '26 Sep 2020' reason for change: Data Entry Error   |                        | 06 Nov 2020 21:58:33 |
| User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).             | System                 | 04 Nov 2020 19:04:37 |
| Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). | System                 | 04 Nov 2020 19:04:37 |
| User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).  | System                 | 04 Nov 2020 19:04:37 |
| User entered '16 Sep 2020' reason for change: Data Entry Error   | Dawn Killian (b) (4)   | 04 Nov 2020 19:04:37 |
| User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).  | System                 | 04 Nov 2020 19:03:51 |
| User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).             | System                 | 04 Nov 2020 19:03:51 |
| User entered empty.  | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

**End time (00:00-23:59)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:13 |
| User entered empty.       | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 11:55:32 |
| User entered empty. | System           | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

[Severity](#)

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded.                  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                        | (b) (4), (b) (6)       | 23 Nov 2020 17:52:15 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

[Is the adverse event serious?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:16 |
| User entered 'No (N)'     | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Death](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:18 |
| User entered '0'          | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

[Life threatening](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:19 |
| User entered '0'          | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |



**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:21 |
| User entered '0'          | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

**Hospital Admission Date** (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:22 |
| User entered empty.       | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:23 |
| User entered empty.       | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Admitted to ICU?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:25 |
| User entered empty.       | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Number of Days in ICU](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:26 |
| User entered empty.       | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

[Persistent or significant disability or incapacity](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:28 |
| User entered '0'          | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

[Congenital anomaly or birth defect](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:29 |
| User entered '0'          | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Other medically important event](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:30 |
| User entered '0'          | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |



**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Relationship to investigational product](#)

| Audit                                    | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded.                | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                      | (b) (4), (b) (6)       | 23 Nov 2020 17:52:32 |
| User entered 'Not Related (NOT RELATED)' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

[Relationship to Study Procedure](#)

| Audit                                    | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded.                | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                      | (b) (4), (b) (6)       | 23 Nov 2020 17:52:33 |
| User entered 'Not Related (NOT RELATED)' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Action taken with investigational product](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 23 Nov 2020 17:52:35 |
| User entered 'None (NONE)' | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

None

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 03 Mar 2021 22:01:28 |
| User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).             | (b) (4), (b) (6)       | 15 Jan 2021 11:27:27 |
| Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Updated' (Site from DM). | (b) (4), (b) (6)       | 14 Jan 2021 22:16:18 |
| DataPoint Un-verified.   | (b) (4), (b) (6)       | 14 Jan 2021 22:16:08 |
| User entered '0' reason for change: Data Entry Error   | (b) (4), (b) (6)       | 14 Jan 2021 22:16:08 |
| User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).             | (b) (4), (b) (6)       | 23 Nov 2020 23:46:58 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 23 Nov 2020 17:52:36 |
| User entered '1'   | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

[Concomitant Medication](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded.                            | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                                  | (b) (4)                |                      |
| DataPoint Un-verified.                               | (b) (4), (b) (6)       | 03 Mar 2021 22:01:20 |
| User entered '1' reason for change: Data Entry Error |                        | 14 Jan 2021 22:16:08 |
| DataPoint Verified.                                  |                        | 14 Jan 2021 22:16:08 |
| User entered '0'                                     |                        | 23 Nov 2020 17:52:37 |
|  | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |
|  | (b) (4)                |                      |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Concomitant Procedure](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:39 |
| User entered '0'          | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

US3292324

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:34:27

[Outcome](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 23 Nov 2020 17:52:40 |
| User entered 'Recovered/Resolved<br>(RECOVERED/RESOLVED)' reason for change:<br>Data Entry Error | Dawn Killian (b) (4)   | 04 Nov 2020 19:03:51 |
| User entered 'Recovering/Resolving<br>(RECOVERING/RESOLVING)'                                    | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[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 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:41 |
| User entered empty.       | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Narrative](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:55:32 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:52:43 |
| User entered empty.       | Kevin Martinez (b) (4) | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:55:32 |
| User entered '0'  | System           | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:55:32 |
| User entered '0'  | System           | 24 Sep 2020 17:17:08 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:55:32 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[AEID](#)

| Audit                                 | User                   | Time (GMT)           |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded.             | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| Reviewed for Safety.                  | (b) (4)                |                      |
|                                       | (b) (4), (b) (6)       | 21 Apr 2021 21:13:10 |
| Un-reviewed for Safety.               | (b) (4), (b) (6)       | 21 Apr 2021 21:13:07 |
| DataPoint Verified.                   | (b) (4), (b) (6)       | 23 Nov 2020 17:54:16 |
| Reviewed for Safety.                  | (b) (4), (b) (6)       | 04 Nov 2020 18:49:02 |
| User entered                          | System                 | 04 Nov 2020 18:48:49 |
| 'USA-US072-2020-mRNA-1273-P301000008' |                        |                      |
| User entered 'New'                    | (b) (4), (b) (6)       | 04 Nov 2020 18:48:49 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Adverse event](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 23 Nov 2020 17:54:17 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Femur fracture, LLT: Fracture femur - version MedDRA\\23.0. | Coder Import (b) (4)   | 04 Nov 2020 15:05:24 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)   | 04 Nov 2020 15:05:24 |
| Data point term sent to Coder  | System                 | 04 Nov 2020 14:44:49 |
| User entered 'R broken femur'  | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Was this a medically-attended AE?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:54:18 |
| User entered 'Yes (Y)'    |                        | 04 Nov 2020 14:43:56 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 23 Nov 2020 17:54:20 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |



US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 23 Nov 2020 17:54:21 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

Start date (dd MMM yyyy)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 23 Nov 2020 17:54:23 |
| User entered '3 Nov 2020' | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 23 Nov 2020 17:54:24 |
| User entered empty.       | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Ongoing?](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User signature succeeded.                                 | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                                       | (b) (4)                | 08 Feb 2021 19:25:39 |
| DataPoint Un-verified.                                    | (b) (4), (b) (6)       | 20 Jan 2021 17:04:20 |
| User entered 'No (N)' reason for change: Data Entry Error |                        | 20 Jan 2021 17:04:20 |
| DataPoint Verified.                                       |                        | 23 Nov 2020 17:54:26 |
| User entered 'Yes (Y)'                                    |                        | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

If not Ongoing, end date (dd MMM yyyy)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.  | (b) (4)                | 08 Feb 2021 19:25:41 |
| 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).              | (b) (4), (b) (6)       | 21 Jan 2021 15:29:04 |
| 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 'provided' (Site from Safety). |                        | 20 Jan 2021 17:04:38 |
| DataPoint Un-verified.   |                        | 20 Jan 2021 17:04:20 |
| User entered '22 Dec 2020' reason for change: Data Entry Error   |                        | 20 Jan 2021 17:04:20 |
| DataPoint Verified.  |                        | 23 Nov 2020 17:54:30 |
| 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).              |                        | 13 Nov 2020 16:31:55 |
| User entered empty.  |                        | 04 Nov 2020 14:43:56 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:34:27**

**End time (00:00-23:59)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:54:32 |
| User entered empty.       |                        | 04 Nov 2020 14:43:56 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:34:27**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Nov 2020 14:43:56 |



US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Severity](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.  | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 08 Feb 2021 19:25:46 |
| User closed query 'PV Query: As the event resulted in hospitalization, please confirm the intensity of grade 3.' (Site from Safety).               |                        | 24 Nov 2020 17:10:36 |
| Query 'PV Query: As the event resulted in hospitalization, please confirm the intensity of grade 3.' answered with 'confirmed' (Site from Safety). | Gerardo Pena (b) (4)   | 23 Nov 2020 19:29:56 |
| User opened query 'PV Query: As the event resulted in hospitalization, please confirm the intensity of grade 3.' (Site from Safety).               | (b) (4)                |                      |
| User entered 'Grade 3/Severe (Grade 3/Severe)'   | (b) (4), (b) (6)       | 13 Nov 2020 16:32:10 |
|  |                        | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Is the adverse event serious?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:54:35 |
| User entered 'Yes (Y)'    |                        | 04 Nov 2020 14:43:56 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Death](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 23 Nov 2020 17:54:37 |
| User entered '0'          | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Life threatening](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 23 Nov 2020 17:54:38 |
| User entered '0'          | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.   | (b) (4)                | 23 Nov 2020 17:54:40 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                                 | (b) (4), (b) (6)       | 23 Nov 2020 15:39:54 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is still admitted. ' (Site from System). |                        | 04 Nov 2020 14:45:30 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).                                 | System                 | 04 Nov 2020 14:43:56 |
| User entered 'I'  | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

Hospital Admission Date (dd MMM yyyy)

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)          | 22 Apr 2021 17:55:13 |
| User signature succeeded.  | Douglas Denham (b) (4)    | 22 Apr 2021 15:51:45 |
| User closed query 'PV Query: Dates of hospitalization are reported as 10 Nov 2020 through 19 Nov 2020 but source documents indicate event took place on 03 Nov 2020 and that subject was admitted on that date with a surgical repair on 04 Nov 2020. Please reconcile this date.' (Site from Safety).   | (b) (4), (b) (6)          | 21 Apr 2021 20:51:27 |
| Query 'PV Query: Dates of hospitalization are reported as 10 Nov 2020 through 19 Nov 2020 but source documents indicate event took place on 03 Nov 2020 and that subject was admitted on that date with a surgical repair on 04 Nov 2020. Please reconcile this date.' answered with 'per patient she was in the hospital from 03/nov/2020 to 19nov2020' (Site from Safety). |                           | 21 Apr 2021 15:16:46 |
| User entered '03 Nov 2020' reason for change: New Information  |                           | 21 Apr 2021 15:11:17 |
| User opened query 'PV Query: Dates of hospitalization are reported as 10 Nov 2020 through 19 Nov 2020 but source documents indicate event took place on 03 Nov 2020 and that subject was admitted on that date with a surgical repair on 04 Nov 2020. Please reconcile this date.' (Site from Safety).   |                           | 02 Apr 2021 13:57:08 |
| DataPoint Un-verified.   | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:37:39 |
| User entered '10 Nov 2020' reason for change: New Information  | Antonio Gutierrez (b) (4) | 24 Mar 2021 20:37:39 |
| DataPoint Verified.  | (b) (4), (b) (6)          | 08 Feb 2021 19:26:58 |
| DataPoint Un-verified.   |                           | 08 Feb 2021 19:26:14 |
| DataPoint Verified.  |                           | 23 Nov 2020 17:54:42 |
| User entered '3 Nov 2020'  |                           | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

Hospital Discharge Date (dd MMM yyyy)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)           | 22 Apr 2021 17:55:10 |
| User closed query 'Comment in Source specifying discharge date is not in source. Please add.' (Site from CRA).   | (b) (4), (b) (6)           | 22 Apr 2021 17:55:07 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 22 Apr 2021 15:51:45 |
| Query 'Comment in Source specifying discharge date is not in source. Please add.' answered with 'Updated' (Site from CRA).   | (b) (4), (b) (6)           | 21 Apr 2021 21:05:27 |
| User opened query 'Comment in Source specifying discharge date is not in source. Please add.' (Site from CRA).   | (b) (4), (b) (6)           | 09 Apr 2021 18:41:57 |
| User closed query 'Please include comment in AE source confirming that the subject was discharged on 19Nov2020' (Site from CRA).   | (b) (4), (b) (6)           | 09 Apr 2021 18:41:57 |
| Query 'Please include comment in AE source confirming that the subject was discharged on 19Nov2020' answered with 'comment added ' (Site from CRA).  | Victoria Hernandez (b) (4) | 24 Mar 2021 15:21:19 |
| User opened query 'Please include comment in AE source confirming that the subject was discharged on 19Nov2020' (Site from CRA).   | (b) (4), (b) (6)           | 03 Mar 2021 22:04:25 |
| User closed query 'Source states that subject was expected to be discharged on 19Nov2020. Please Provide comment confirming discharge.' (Site from CRA).                                       | (b) (4), (b) (6)           | 03 Mar 2021 22:04:25 |
| Query 'Source states that subject was expected to be discharged on 19Nov2020. Please Provide comment confirming discharge.' answered with 'Discharge date has been provided.' (Site from CRA). | (b) (4), (b) (6)           | 18 Feb 2021 17:02:12 |
| User opened query 'Source states that subject was expected to be discharged on 19Nov2020. Please Provide comment confirming discharge.' (Site from CRA).                                       | (b) (4), (b) (6)           | 08 Feb 2021 19:27:47 |
| User closed query 'PV Query: Please provide hospital discharge date when available.' (Site from Safety).   | (b) (4), (b) (6)           | 11 Dec 2020 13:51:03 |
| Query 'PV Query: Please provide hospital discharge date when available.' answered with 'updated' (Site from Safety).   | (b) (4), (b) (6)           | 10 Dec 2020 20:53:16 |
| DataPoint Un-verified.   | (b) (4), (b) (6)           | 10 Dec 2020 20:52:40 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered '19 Nov 2020' reason for change: Data Entry Error<br>DataPoint Verified.                    | (b) (4), (b) (6) | 10 Dec 2020 20:52:40 |
|  |                  | 23 Nov 2020 17:54:47 |
| User opened query 'PV Query: Please provide hospital discharge date when available.' (Site from Safety). |                  | 13 Nov 2020 16:31:46 |
| User entered empty.  |                  | 04 Nov 2020 14:43:56 |



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Admitted to ICU?](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.   | (b) (4)                |                      |
|   | (b) (4), (b) (6)       | 23 Nov 2020 17:57:03 |
| User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).                    | System                 | 04 Nov 2020 14:45:41 |
| Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System). |                        | 04 Nov 2020 14:45:41 |
| User entered 'No (N)' reason for change: Data Entry Error   | (b) (4), (b) (6)       | 04 Nov 2020 14:45:41 |
| User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).                    | System                 | 04 Nov 2020 14:43:56 |
| User entered 'Unknown (UNK)'  | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Number of Days in ICU](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 23 Nov 2020 17:57:05 |
| User entered empty.       | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Persistent or significant disability or incapacity](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 23 Nov 2020 17:57:06 |
| User entered '0'          | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Congenital anomaly or birth defect](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 23 Nov 2020 17:57:08 |
| User entered '0'          | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Other medically important event](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 23 Nov 2020 17:57:09 |
| User entered '0'          |                        | 04 Nov 2020 14:43:56 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Relationship to investigational product](#)

| Audit                                    | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.                | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                      | (b) (4), (b) (6)       | 23 Nov 2020 17:57:10 |
| User entered 'Not Related (NOT RELATED)' |                        | 04 Nov 2020 14:43:56 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Relationship to Study Procedure](#)

| Audit                                    | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.                | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                      | (b) (4)                | 23 Nov 2020 17:57:12 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Action taken with investigational product](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                      | Douglas Denham (b) (4)      | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                            | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 17:57:13 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Antonio Gutierrez (b) (4)   | 04 Nov 2020 15:21:39 |
| reason for change: Data Entry Error            |                             |                      |
| User entered 'None (NONE)'                     | (b) (4), (b) (6)            | 04 Nov 2020 14:43:56 |



**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:34:27**

[None](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 23 Nov 2020 17:57:16 |
| User entered '0'          | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Concomitant Medication](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User closed query 'PV Query: Please confirm that the subject did not require any treatment medications (i.e. pain medications). If treatment medications were given, please add to concomitant medication eCRF.' (Site from Safety).                          | (b) (4), (b) (6)       | 22 Feb 2021 16:29:04 |
| Query 'PV Query: Please confirm that the subject did not require any treatment medications (i.e. pain medications). If treatment medications were given, please add to concomitant medication eCRF.' answered with 'No medications taken' (Site from Safety). |                        | 18 Feb 2021 17:24:56 |
| User opened query 'PV Query: Please confirm that the subject did not require any treatment medications (i.e. pain medications). If treatment medications were given, please add to concomitant medication eCRF.' (Site from Safety).                          |                        | 08 Feb 2021 21:04:01 |
| DataPoint Verified.   |                        | 23 Nov 2020 17:56:59 |
| User entered '0'  |                        | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Concomitant Procedure](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per Narrative, Patient was taken to the OR for Surgery for Repair. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).                        | (b) (4), (b) (6)       | 25 Jan 2021 08:53:49 |
| Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per Narrative, Patient was taken to the OR for Surgery for Repair. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'procedure provided' (Site from DM). | (b) (4), (b) (6)       | 20 Jan 2021 17:08:00 |
| User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Per Narrative, Patient was taken to the OR for Surgery for Repair. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).                        | (b) (4), (b) (6)       | 23 Nov 2020 23:47:59 |
| DataPoint Verified.   | (b) (4), (b) (6)       | 23 Nov 2020 17:56:57 |
| Query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' canceled (Site from DM).  | (b) (4), (b) (6)       | 23 Nov 2020 15:39:59 |
| User opened query 'Per CDM: Concomitant Procedures check box "checked" however concomitant Procedures eCRF has not been updated? Please review and update accordingly.' (Site from DM).   | (b) (4), (b) (6)       | 14 Nov 2020 22:47:14 |
| User entered 'I'  | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Outcome](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.  | (b) (4)                | 08 Feb 2021 19:28:06 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).              | (b) (4), (b) (6)       | 21 Jan 2021 15:29:10 |
| Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'provided' (Site from Safety). |                        | 20 Jan 2021 17:05:14 |
| DataPoint Un-verified.   |                        | 20 Jan 2021 17:04:20 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:  |                        | 20 Jan 2021 17:04:20 |
| Data Entry Error   |                        |                      |
| DataPoint Verified.  |                        | 23 Nov 2020 17:56:55 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).              |                        | 13 Nov 2020 16:31:36 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'   |                        | 04 Nov 2020 14:43:56 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 23 Nov 2020 17:56:50 |
| User entered empty.       | (b) (4), (b) (6)       | 04 Nov 2020 14:43:56 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Narrative](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User closed query 'Per CDM: Per previous query response "UPDATED"; however, the correction/update is not obvious please provide location of update such as the form/log line number/data field corrected/updated. Thank you.' (Site from DM).                         | (b) (4), (b) (6)       | 29 Apr 2021 09:52:28 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| Query 'Per CDM: Per previous query response "UPDATED"; however, the correction/update is not obvious please provide location of update such as the form/log line number/data field corrected/updated. Thank you.' answered with 'Fall updated as AE' (Site from DM).  | (b) (4), (b) (6)       | 21 Apr 2021 21:26:04 |
| User opened query 'Per CDM: Per previous query response "UPDATED"; however, the correction/update is not obvious please provide location of update such as the form/log line number/data field corrected/updated. Thank you.' (Site from DM).                         |                        | 26 Mar 2021 16:42:05 |
| User closed query 'Per DM CLR: Narrative indicates that this AE was a result of FALL. However, there is no corresponding AE record of FALL that match the information. Please update to record the corresponding AE appropriate. Otherwise, clarify.' (Site from DM). |                        | 26 Mar 2021 16:42:05 |
| User closed query 'PV Query: Thank you for confirming fall as an SAE. Please add SAE to the EDC as soon as possible.' (Site from Safety).   |                        | 25 Mar 2021 15:39:53 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).   |                        | 25 Mar 2021 15:39:49 |
| User closed query 'PV Query: Please confirm if the fall was a mechanical fall or if the subject experienced dizziness/lightheadedness/etc.' (Site from Safety).   |                        | 25 Mar 2021 15:39:46 |
| User closed query 'PV Query: Please provide the results of any imaging performed related to the event.' (Site from Safety).   |                        | 25 Mar 2021 15:39:43 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Narrative](#)

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No testing is shown in medical records received. However, patient states she was tested upon admission and the test was negative. Unknown test type.' (Site from Safety). | Antonio Gutierrez (b) (4)  | 24 Mar 2021 20:50:33 |
| Query 'PV Query: Please provide the results of any imaging performed related to the event.' answered with 'X-ray showed a comminuted fracture of the distal right femur.' (Site from Safety).  | Antonio Gutierrez (b) (4)  | 24 Mar 2021 20:40:51 |
| Query 'PV Query: Please confirm if the fall was a mechanical fall or if the subject experienced dizziness/lightheadedness/etc.' answered with 'fall was mechanical' (Site from Safety).  | Victoria Hernandez (b) (4) | 24 Mar 2021 16:04:42 |
| Query 'PV Query: Thank you for confirming fall as an SAE. Please add SAE to the EDC as soon as possible.' answered with 'updated' (Site from Safety).  | Victoria Hernandez (b) (4) | 24 Mar 2021 16:04:01 |
| Query 'Per DM CLR: Narrative indicates that this AE was a result of FALL. However, there is no corresponding AE record of FALL that match the information. Please update to record the corresponding AE appropriate. Otherwise, clarify.' answered with 'Fall documented as separate AE' (Site from DM).   | Victoria Hernandez (b) (4) | 24 Mar 2021 16:03:43 |
| User opened query 'PV Query: Thank you for confirming fall as an SAE. Please add SAE to the EDC as soon as possible.' (Site from Safety).  | (b) (4), (b) (6)           | 25 Feb 2021 20:34:59 |
| User closed query 'PV Query: Thank you for confirming fall as an SAE. Please report this in EDC as soon as possible.' (Site from Safety).  | (b) (4), (b) (6)           | 22 Feb 2021 16:29:13 |
| User closed query 'PV Query: Please provide the name/date of surgical procedure.' (Site from Safety).  | (b) (4), (b) (6)           | 22 Feb 2021 16:29:09 |
| Query 'PV Query: Thank you for confirming fall as an SAE. Please report this in EDC as soon as possible.' answered with 'reported' (Site from Safety).   | Gerardo Pena (b) (4)       | 19 Feb 2021 22:58:34 |
| Query 'PV Query: Please provide the name/date of surgical procedure.' answered with 'information in concomitant procedures section.' (Site from Safety).   | Gerardo Pena (b) (4)       | 19 Feb 2021 22:57:31 |

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Folder: Adverse Events

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[Narrative](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User opened query 'Per DM CLR: Narrative indicates that this AE was a result of FALL. However, there is no corresponding AE record of FALL that match the information. Please update to record the corresponding AE appropriate. Otherwise, clarify.' (Site from DM).   | (b) (4), (b) (6) | 16 Feb 2021 11:33:13 |
| User opened query 'PV Query: Thank you for confirming fall as an SAE. Please report this in EDC as soon as possible.' (Site from Safety).   |                  | 08 Feb 2021 21:07:45 |
| User opened query 'PV Query: Please provide the name/date of surgical procedure.' (Site from Safety).   |                  | 08 Feb 2021 21:03:35 |
| User closed query 'PV Query: Please provide treatment for the event (including name/date of surgical procedure) and any treatment medications. Please add treatment medications to CM eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).  |                  | 04 Feb 2021 12:39:41 |
| Query 'PV Query: Please provide treatment for the event (including name/date of surgical procedure) and any treatment medications. Please add treatment medications to CM eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Subject is started Physical Therapy on 22 Dec 2020' (Site from Safety). |                  | 03 Feb 2021 22:27:08 |
| User closed query 'PV Query: Please confirm if fall meets criteria for separate AE/SAE reporting.' (Site from Safety).  |                  | 21 Jan 2021 15:29:18 |
| User closed query 'PV Query: Is shingles considered med history (prior to start of study)? If so, please add to MH eCRF.' (Site from Safety).   |                  | 21 Jan 2021 15:29:15 |
| Query 'PV Query: Please confirm if fall meets criteria for separate AE/SAE reporting.' answered with 'SAE reported.' (Site from Safety).  |                  | 20 Jan 2021 17:14:15 |
| Query 'PV Query: Is shingles considered med history (prior to start of study)? If so, please add to MH eCRF.' answered with 'No, AE added' (Site from Safety).  |                  | 20 Jan 2021 17:13:27 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).   |                  | 16 Dec 2020 15:03:32 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Narrative](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6) | 23 Nov 2020 17:56:53 |
| User opened query 'PV Query: Please confirm if the fall was a mechanical fall or if the subject experienced dizziness/lightheadedness/etc.' (Site from Safety).  |                  | 13 Nov 2020 16:32:31 |
| User opened query 'PV Query: Please confirm if fall meets criteria for separate AE/SAE reporting.' (Site from Safety).   |                  | 13 Nov 2020 16:32:27 |
| User opened query 'PV Query: Please provide treatment for the event (including name/date of surgical procedure) and any treatment medications. Please add treatment medications to CM eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).   |                  | 13 Nov 2020 16:32:17 |
| User opened query 'PV Query: Please provide the results of any imaging performed related to the event.' (Site from Safety).  |                  | 13 Nov 2020 16:32:03 |
| User opened query 'PV Query: Is shingles considered med history (prior to start of study)? If so, please add to MH eCRF.' (Site from Safety).  |                  | 13 Nov 2020 16:31:30 |
| User entered 'SUBJECT CALLED TO INFORM US sHE IS CURRENTLY ADMITTED AT METROPOLITAN METHODIST FOR A BROKEN FEMUR. SHE STATES SHE BROKE HER FEMUR YESTERDAY(03-NOV-2020) DURING A FALL PICKING UP HER GROCERIES. SHE WENT TO THE ER (AT HOSPITAL STATED ABOVE) AND WAS TAKEN TO THE OR FOR SURGERY FOR REPAIR. SHE IS CURRENTLY STAYING FOR OBSERVATION AND IS EXPECTED TO STAY FOR ABOUT 3-4 DAYS. RECORDS WILL BE REQUESTED.' reason for change: Data Entry Error |                  | 04 Nov 2020 14:46:19 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

[Narrative](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User entered 'Subject called to inform us he is currently admitted at Metropolitan Methodist for a broken femur. She states she broke her femur yesterday(03-Nov-2020) during a fall picking up her groceries. She went to the ER (at hospital stated above) and was taken to the OR for surgery for repair. She is currently staying for observation and is expected to stay for about 3-4 days. <br />Records will be requested.' | (b) (4), (b) (6) | 04 Nov 2020 14:43:56 |

US3292324

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:34:27

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 04 Nov 2020 14:43:56 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 04 Nov 2020 14:43:56 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 04 Nov 2020 14:43:56 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:56:02 |

US3292324

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:34:27

[Adverse event](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 29 Apr 2021 11:56:02 |
| User signature succeeded.   | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 08 Feb 2021 19:28:32 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 20 Jan 2021 17:14:05 |
| 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 Jan 2021 17:14:05 |
| Data point term sent to Coder   | System                          | 20 Jan 2021 17:12:58 |
| User entered 'Shingles'   | (b) (4), (b) (6)                | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Was this a medically-attended AE?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:28:34 |
| User entered 'Yes (Y)'    |                        | 20 Jan 2021 17:12:43 |



**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:28:36 |
| User entered 'No (N)'     |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4)<br>(b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)                  | 08 Feb 2021 19:28:39 |
| User entered 'No (N)'     |                                   | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4)                |                      |
|                            | (b) (4), (b) (6)       | 08 Feb 2021 19:28:30 |
| User entered '14 Sep 2020' |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:28:41 |
| User entered empty.       |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 11:56:02 |
| User entered empty. | System           | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Ongoing?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:28:43 |
| User entered 'No (N)'     |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 29 Apr 2021 11:56:02 |
| User signature succeeded.  | Douglas Denham (b) (4)<br>(b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4), (b) (6)                  | 08 Feb 2021 19:28:44 |
| User entered '24 Sep 2020' |                                   | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

**End time (00:00-23:59)**

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4)<br>(b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)                  | 08 Feb 2021 19:28:45 |
| User entered empty.       |                                   | 20 Jan 2021 17:12:43 |



US3292324

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:34:27

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 11:56:02 |
| User entered empty. | System           | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Severity](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded.                          | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                                | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 08 Feb 2021 19:28:47 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Is the adverse event serious?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:28:48 |
| User entered 'No (N)'     |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Death](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 08 Feb 2021 19:28:50 |
| User entered '0'          | (b) (4), (b) (6)       | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Life threatening](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 03 Mar 2021 22:04:37 |
| User entered '0'          |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 08 Feb 2021 19:28:53 |
| User entered '0'          | (b) (4), (b) (6)       | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

**Hospital Admission Date** (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:28:55 |
| User entered empty.       |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

**Hospital Discharge Date** (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:28:56 |
| User entered empty.       |                        | 20 Jan 2021 17:12:43 |



**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Admitted to ICU?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:28:58 |
| User entered empty.       |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Number of Days in ICU](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:28:59 |
| User entered empty.       |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:29:01 |
| User entered '0'          |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Congenital anomaly or birth defect](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:29:02 |
| User entered '0'          |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Other medically important event](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:29:05 |
| User entered '0'          |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Relationship to investigational product](#)

| Audit                                    | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded.                | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                      | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 08 Feb 2021 19:29:09 |
| User entered 'Not Related (NOT RELATED)' |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Relationship to Study Procedure](#)

| Audit                                    | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded.                | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                      | (b) (4)                | 08 Feb 2021 19:29:10 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6)       | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Action taken with investigational product](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4)                |                      |
|                            | (b) (4), (b) (6)       | 08 Feb 2021 19:29:12 |
| User entered 'None (NONE)' |                        | 20 Jan 2021 17:12:43 |



**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[None](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:29:18 |
| User entered '0'          |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Concomitant Medication](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:29:21 |
| User entered 'l'          |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Concomitant Procedure](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:29:30 |
| User entered '0'          |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Outcome](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded.                                 | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                                       | (b) (4)                |                      |
|   | (b) (4), (b) (6)       | 08 Feb 2021 19:29:29 |
| User entered 'Recovered/Resolved<br>(RECOVERED/RESOLVED)' |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[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 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:29:32 |
| User entered empty.       |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Narrative](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:02 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                |                      |
|                           | (b) (4), (b) (6)       | 08 Feb 2021 19:29:34 |
| User entered empty.       |                        | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

**Serious Adverse Event Derived (CSA Programming Field Only)**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:56:02 |
| User entered '0'  | System           | 20 Jan 2021 17:12:43 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:56:02 |
| User entered 'I'  | System           | 20 Jan 2021 17:12:43 |



US3292324

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:34:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:56:02 |

US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:56:07 |

US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[Adverse event](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 29 Apr 2021 11:56:07 |
| DataPoint Verified.  |                                 | 22 Apr 2021 22:24:41 |
| User signature succeeded.  | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| 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. | (b) (4)<br>Coder Import (b) (4) | 21 Apr 2021 21:26:31 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)            | 21 Apr 2021 21:26:31 |
| Data point term sent to Coder  | System                          | 21 Apr 2021 21:25:54 |
| User entered 'Fall'  | (b) (4), (b) (6)                | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Was this a medically-attended AE?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

Start date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.        |                        | 22 Apr 2021 22:24:41 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered '03 Nov 2020' | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

Start time (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       |                             | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Apr 2021 15:51:45 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 21:25:16 |



US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 11:56:07 |
| User entered empty. | System           | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Ongoing?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

If not Ongoing, end date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.        | (b) (4)                | 22 Apr 2021 22:24:41 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered '03 Nov 2020' | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

**End time (00:00-23:59)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered empty.       | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 11:56:07 |
| User entered empty. | System           | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Severity](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                              | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.                            |                        | 22 Apr 2021 22:24:41 |
| User signature succeeded.                      | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered 'Grade 3/Severe (Grade 3/Severe)' | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[Is the adverse event serious?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       |                        | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Death](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered '0'          | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |



US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Apr 2021 15:51:45 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 21:25:16 |

US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       |                             | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Apr 2021 15:51:45 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

**Hospital Admission Date** (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered empty.       | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

Hospital Discharge Date (dd MMM yyyy)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       |                        | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered empty.       | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Admitted to ICU?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       |                        | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered empty.       | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       | (b) (4), (b) (6)            | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Apr 2021 15:51:45 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 21:25:16 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       |                             | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4)      | 22 Apr 2021 15:51:45 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Congenital anomaly or birth defect](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       |                        | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered '0'          | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |



US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[Other medically important event](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       |                        | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered '0'          | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[Relationship to investigational product](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.  | (b) (4)                | 22 Apr 2021 22:24:41 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)                |                      |
|  | System                 | 21 Apr 2021 21:25:27 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 21 Apr 2021 21:25:27 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | (b) (4), (b) (6)       | 21 Apr 2021 21:25:27 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 21 Apr 2021 21:25:16 |
| User entered empty.  | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[Relationship to Study Procedure](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.  | (b) (4)                | 22 Apr 2021 22:24:41 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)                |                      |
|  | System                 | 21 Apr 2021 21:25:27 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 21 Apr 2021 21:25:27 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error           | (b) (4), (b) (6)       | 21 Apr 2021 21:25:27 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 21 Apr 2021 21:25:16 |
| User entered empty.  | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

Action taken with investigational product

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 22 Apr 2021 22:24:41 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| 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                 | 21 Apr 2021 21:25:27 |
| User entered 'None (NONE)' reason for change: Data Entry Error                         | System                 | 21 Apr 2021 21:25:27 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |
| User entered empty.  | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[None](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       |                        | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered 'l'          | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Concomitant Medication](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       |                        | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered '0'          | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Concomitant Procedure](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       |                        | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered '0'          | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[Outcome](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 22 Apr 2021 22:24:41 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)                |                      |
|  | System                 | 21 Apr 2021 21:25:35 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 21 Apr 2021 21:25:35 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:              | (b) (4), (b) (6)       | 21 Apr 2021 21:25:35 |
| Data Entry Error   |                        |                      |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                 | 21 Apr 2021 21:25:16 |
| User entered empty.  | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |



**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[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 11:56:07 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered empty.       | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Narrative](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 29 Apr 2021 11:56:07 |
| DataPoint Verified.       |                        | 22 Apr 2021 22:24:41 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered empty.       | (b) (4), (b) (6)       | 21 Apr 2021 21:25:16 |

**US3292324**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:56:07 |
| User entered '0'  | System           | 21 Apr 2021 21:25:16 |

US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

Medically Attended AE Derived (CSA Programming Field Only)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:56:07 |
| User entered 'I'  | System           | 21 Apr 2021 21:25:16 |

US3292324

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:34:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:56:07 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:34:27

Were any prior/concomitant medications and/or vaccinations taken?

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 03 May 2021 05:13:34 |
| User signature succeeded.   | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.   | (b) (4)                |                      |
|   | (b) (4), (b) (6)       | 11 Feb 2021 19:12:55 |
| User closed query 'Per CDM: Please update medication used for dairy dose 2 day 2' (Site from DM).             |                        | 11 Nov 2020 12:20:34 |
| Query 'Per CDM: Please update medication used for dairy dose 2 day 2' answered with 'updated' (Site from DM). | Dawn Killian (b) (4)   | 08 Oct 2020 19:37:54 |
| User opened query 'Per CDM: Please update medication used for dairy dose 2 day 2' (Site from DM).             | (b) (4)                |                      |
|   | (b) (4), (b) (6)       | 29 Sep 2020 11:56:57 |
| User entered 'Yes (Y)'  |                        | 28 Aug 2020 13:11:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:34:27

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 11 Feb 2021 19:13:24 |
| 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 18:58:47 |
| 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 18:58:47 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:34:27

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 17:30:47 |
| 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 17:30:47 |



US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:34:27

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) | 09 Sep 2020 14:14:48 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4) | 09 Sep 2020 14:14:48 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, COMBINATIONS, ATC: MULTIVITAMINS WITH MINERALS, PRODUCT: ASCORBIC ACID;BETACAROTENE;BIOTIN;CALCIUM;CHLORINE;CHROMIUM;COPPER;CYANOCOBALAMIN;DL-ALPHA TOCOPHERYL ACETATE;FOLIC ACID;IODINE;MAGNESIUM;MANGANESE;MOLYBDENUM;NICKEL;NICOTINAMIDE;PANTOTHENIC ACID;PHOSPHORUS;PHYTOMENADIONE;POTASSIUM;PYRIDOXINE HYDROCHLORIDE;RETINOL;RIBOFLAVIN;SELENIUM;SILICON;THIAMINE;VANADIUM;VITAMIN D NOS;XANTOXYL;ZINC, PRODUCTSYNONYM: CENTRUM SILVER +50 - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 28 Aug 2020 13:13:41 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4) | 28 Aug 2020 13:13:41 |
| Data point term sent to Coder  | System               | 28 Aug 2020 13:12:19 |
| User entered 'centrum silver'  | (b) (4), (b) (6)     | 28 Aug 2020 13:11:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:34:27

[Prophylaxis](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.   | (b) (4)                |                      |
|   | (b) (4), (b) (6)       | 11 Feb 2021 19:13:24 |
| 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).             |                        | 29 Dec 2020 21:19:18 |
| 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). | Dawn Killian (b) (4)   | 21 Dec 2020 19:40:56 |
|   | (b) (4)                |                      |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Dawn Killian (b) (4)   | 21 Dec 2020 19:40:49 |
|   | (b) (4)                |                      |
| 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)       | 28 Nov 2020 18:13:43 |
| User entered 'No (N)'   |                        | 28 Aug 2020 13:11:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:34:27

[Indication](#)

| Audit                                 | User                   | Time (GMT)           |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded.             | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                   | (b) (4)                | 11 Feb 2021 19:13:24 |
| User entered 'nutritional supplement' | (b) (4), (b) (6)       | 28 Aug 2020 13:11:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:34:27

[Dose per administration](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:13:24 |
| User entered 'l'          | (b) (4), (b) (6)       | 28 Aug 2020 13:11:39 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Dose unit](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.            | (b) (4)                | 11 Feb 2021 19:13:24 |
| User entered 'tablet (TABLET)' | (b) (4), (b) (6)       | 28 Aug 2020 13:11:39 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:34:27**

[If dose unit is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:13:24 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:11:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:34:27

[Frequency](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.            | (b) (4)                | 11 Feb 2021 19:13:24 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)       | 28 Aug 2020 13:11:39 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:34:27**

[If frequency is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:13:24 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:11:39 |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:34:27

[Route of administration](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4)                | 11 Feb 2021 19:13:24 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)       | 28 Aug 2020 13:11:39 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:34:27**

[If route of administration is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:13:24 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:11:39 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4)                | 11 Feb 2021 19:13:24 |
| User entered 'un UNK 2010' | (b) (4), (b) (6)       | 28 Aug 2020 13:11:39 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:13:24 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 13:11:39 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Ongoing?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:13:24 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 28 Aug 2020 13:11:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:34:27

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:13:24 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:11:39 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:13:24 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 28 Aug 2020 13:11:39 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 28 Aug 2020 13:11:39 |



US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 28 Aug 2020 13:11:39 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 28 Aug 2020 13:11:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:34:27

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 11 Feb 2021 19:13:53 |
| User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\202003. | Coder Import (b) (4)<br>(b) (4) | 28 Aug 2020 13:23:41 |
| 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) | 28 Aug 2020 13:23:41 |
| Data point term sent to Coder   | System                          | 28 Aug 2020 13:22:35 |
| User entered 'B12' reason for change: Data Entry Error  | (b) (4), (b) (6)                | 28 Aug 2020 13:22:10 |
| Data point term sent to Coder   | System                          | 28 Aug 2020 13:13:24 |
| User entered 'Biz'  | (b) (4), (b) (6)                | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:34:27

[Prophylaxis](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.   | (b) (4)                |                      |
|   | (b) (4), (b) (6)       | 11 Feb 2021 19:13:53 |
| 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).             |                        | 29 Dec 2020 21:19:40 |
| 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). | Dawn Killian (b) (4)   | 21 Dec 2020 19:41:09 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | (b) (4)                |                      |
| 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)       | 28 Nov 2020 18:14:49 |
| User entered 'No (N)'   |                        | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:34:27

[Indication](#)

| Audit                                 | User                   | Time (GMT)           |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded.             | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                   | (b) (4)                | 11 Feb 2021 19:13:53 |
| User entered 'nutritional supplement' | (b) (4), (b) (6)       | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:34:27

[Dose per administration](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.   | (b) (4)                |                      |
|   | (b) (4), (b) (6)       | 11 Feb 2021 19:13:53 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).             |                        | 28 Nov 2020 18:14:41 |
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'unknown' (Site from DM). | Dawn Killian (b) (4)   | 24 Sep 2020 01:05:54 |
|   | (b) (4)                |                      |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).             | (b) (4), (b) (6)       | 22 Sep 2020 11:12:10 |
| User entered 'I'  |                        | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:34:27

[Dose unit](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.            | (b) (4), (b) (6)       | 11 Feb 2021 19:13:53 |
| User entered 'tablet (TABLET)' |                        | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:34:27

If dose unit is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:13:53 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:13:00 |



US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:34:27

[Frequency](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.            | (b) (4)                | 11 Feb 2021 19:13:53 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)       | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:34:27

If frequency is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:13:53 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:34:27

[Route of administration](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4)                | 11 Feb 2021 19:13:53 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)       | 28 Aug 2020 13:13:00 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:34:27**

If route of administration is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:13:53 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:34:27

Start date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 11 Feb 2021 19:13:53 |
| User entered 'un UNK 2015' |                        | 28 Aug 2020 13:13:00 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:13:53 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 13:13:00 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Ongoing?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:13:53 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 28 Aug 2020 13:13:00 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:34:27**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 11 Feb 2021 19:13:53 |
| User entered empty.       |                        | 28 Aug 2020 13:13:00 |



US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 11 Feb 2021 19:13:53 |
| User entered 'No (N)'     |                        | 28 Aug 2020 13:13:00 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 28 Aug 2020 13:13:00 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 28 Aug 2020 13:13:00 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 28 Aug 2020 13:13:00 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:34:27

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)     | 11 Feb 2021 19:14:19 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 28 Aug 2020 13:15:40 |
| 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) | 28 Aug 2020 13:15:40 |
| Data point term sent to Coder  | System                          | 28 Aug 2020 13:14:25 |
| User entered 'biotin'  | (b) (4), (b) (6)                | 28 Aug 2020 13:13:31 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:34:27

[Prophylaxis](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.   | (b) (4)                |                      |
|   | (b) (4), (b) (6)       | 11 Feb 2021 19:14:21 |
| 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).             |                        | 29 Dec 2020 21:20:03 |
| 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). | Dawn Killian (b) (4)   | 21 Dec 2020 19:41:22 |
|   | (b) (4)                |                      |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | Dawn Killian (b) (4)   | 21 Dec 2020 19:41:17 |
|   | (b) (4)                |                      |
| 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)       | 28 Nov 2020 18:16:26 |
| User entered 'No (N)'   |                        | 28 Aug 2020 13:13:31 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:34:27

[Indication](#)

| Audit                                 | User                   | Time (GMT)           |
|---------------------------------------|------------------------|----------------------|
| User signature succeeded.             | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                   | (b) (4)                | 11 Feb 2021 19:14:22 |
| User entered 'nutritional supplement' | (b) (4), (b) (6)       | 28 Aug 2020 13:13:31 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:34:27

[Dose per administration](#)

| Audit  | User                                  | Time (GMT)           |
|--|---------------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)                | 22 Apr 2021 15:51:45 |
| User closed query 'per source, dose amount is 1. Please review and update accordingly.' (Site from CRA).             | (b) (4)<br>(b) (4), (b) (6)           | 25 Mar 2021 21:02:49 |
| DataPoint Verified.  | (b) (4), (b) (6)                      | 25 Mar 2021 21:02:47 |
| Query 'per source, dose amount is 1. Please review and update accordingly.' answered with 'updated' (Site from CRA). | Victoria Hernandez (b) (4)<br>(b) (4) | 24 Mar 2021 16:32:20 |
| User entered '1' reason for change: Data Entry Error   | Victoria Hernandez (b) (4)<br>(b) (4) | 24 Mar 2021 16:32:15 |
| User opened query 'per source, dose amount is 1. Please review and update accordingly.' (Site from CRA).             | (b) (4), (b) (6)                      | 11 Feb 2021 19:17:27 |
| User entered '5000'  |                                       | 28 Aug 2020 13:13:31 |



US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:34:27

[Dose unit](#)

| Audit   | User  | Time (GMT)                                   |
|---|---|--|
| User signature succeeded.   | Douglas Denham (b) (4)                          | 22 Apr 2021 15:51:45                         |
| User closed query 'per source, dose unit is tab. Please review and update accordingly.' (Site from CRA).<br>DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)<br>(b) (4), (b) (6) | 25 Mar 2021 21:02:53<br>25 Mar 2021 21:02:51 |
| Query 'per source, dose unit is tab. Please review and update accordingly.' answered with 'updated' (Site from CRA).  | Victoria Hernandez (b) (4)<br>(b) (4)           | 24 Mar 2021 16:32:24                         |
| User entered 'tablet (TABLET)' reason for change: Data Entry Error  | Victoria Hernandez (b) (4)<br>(b) (4)           | 24 Mar 2021 16:32:15                         |
| User opened query 'per source, dose unit is tab. Please review and update accordingly.' (Site from CRA).  | (b) (4), (b) (6)                                | 11 Feb 2021 19:17:43                         |
| 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. Otherwise, confirm if the unit should be updated to 'ug'. ' (Site from DM).             |   | 28 Nov 2020 18:16:16                         |
| 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. Otherwise, confirm if the unit should be updated to 'ug'. ' answered with 'updated' (Site from DM). | Dawn Killian (b) (4)<br>(b) (4)                 | 24 Sep 2020 01:06:42                         |
| User entered 'ug (ug)' reason for change: Data Entry Error  | Dawn Killian (b) (4)<br>(b) (4)                 | 24 Sep 2020 01:06:36                         |
| 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. Otherwise, confirm if the unit should be updated to 'ug'. ' (Site from DM).             | (b) (4), (b) (6)                                | 22 Sep 2020 11:16:47                         |
| User entered 'mg (mg)'  |   | 28 Aug 2020 13:13:31                         |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:34:27**

[If dose unit is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:17:46 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:13:31 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:34:27

[Frequency](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.            | (b) (4)                | 11 Feb 2021 19:17:47 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)       | 28 Aug 2020 13:13:31 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:34:27

If frequency is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:17:49 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:13:31 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Route of administration](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4)                | 11 Feb 2021 19:17:51 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)       | 28 Aug 2020 13:13:31 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:34:27**

If route of administration is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:17:52 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:13:31 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:34:27

Start date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 11 Feb 2021 19:17:54 |
| User entered '20 Aug 2020' |                        | 28 Aug 2020 13:13:31 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 11 Feb 2021 19:17:56 |
| User entered '0'          |                        | 28 Aug 2020 13:13:31 |



US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:34:27

[Ongoing?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:17:57 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 28 Aug 2020 13:13:31 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:34:27**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:17:59 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:13:31 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:18:02 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 28 Aug 2020 13:13:31 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 28 Aug 2020 13:13:31 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 28 Aug 2020 13:13:31 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 28 Aug 2020 13:13:31 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:34:27

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)     | 11 Feb 2021 19:18:48 |
| User coded data point as ATC: SYSTEMIC<br>HORMONAL PREPARATIONS, EXCL. SEX<br>HORMONES AND INSULINS, ATC: THYROID<br>THERAPY, ATC: THYROID PREPARATIONS,<br>ATC: THYROID HORMONES, PRODUCT:<br>LEVOTHYROXINE SODIUM,<br>PRODUCTSYNONYM: SYNTHROID - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 28 Aug 2020 13:15:40 |
| 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) | 28 Aug 2020 13:15:40 |
| Data point term sent to Coder   | System                          | 28 Aug 2020 13:14:25 |
| User entered 'synthroid'  | (b) (4), (b) (6)                | 28 Aug 2020 13:14:01 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:34:27

[Prophylaxis](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:18:48 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 28 Aug 2020 13:14:01 |



US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Indication](#)

| Audit                         | User                   | Time (GMT)           |
|-------------------------------|------------------------|----------------------|
| User signature succeeded.     | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.           | (b) (4)                | 11 Feb 2021 19:18:48 |
| User entered 'thyroid cancer' | (b) (4), (b) (6)       | 28 Aug 2020 13:14:01 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Dose per administration](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:18:48 |
| User entered '200'        | (b) (4), (b) (6)       | 28 Aug 2020 13:14:01 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:34:27

[Dose unit](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:18:48 |
| User entered 'ug (ug)'    | (b) (4), (b) (6)       | 28 Aug 2020 13:14:01 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:34:27**

[If dose unit is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:18:48 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:14:01 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:34:27

[Frequency](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| User signature succeeded.      | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.            | (b) (4), (b) (6)       | 11 Feb 2021 19:18:48 |
| User entered 'once daily (QD)' |                        | 28 Aug 2020 13:14:01 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:34:27

If frequency is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:18:48 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:14:01 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Route of administration](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4)                | 11 Feb 2021 19:18:48 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)       | 28 Aug 2020 13:14:01 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:34:27**

If route of administration is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:18:48 |
| User entered empty.       | (b) (4), (b) (6)       | 28 Aug 2020 13:14:01 |



US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4)                | 11 Feb 2021 19:18:48 |
| User entered 'un UNK 2014' | (b) (4), (b) (6)       | 28 Aug 2020 13:14:01 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:18:48 |
| User entered '0'          | (b) (4), (b) (6)       | 28 Aug 2020 13:14:01 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Ongoing?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:18:48 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)       | 28 Aug 2020 13:14:01 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:34:27

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 11 Feb 2021 19:18:48 |
| User entered empty.       |                        | 28 Aug 2020 13:14:01 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:18:48 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 28 Aug 2020 13:14:01 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 28 Aug 2020 13:14:01 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 28 Aug 2020 13:14:01 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 28 Aug 2020 13:14:01 |



US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:34:27

[Name of Medication](#)

| Audit   | User                                       | Time (GMT)                                   |
|---|--|--|
| Data hard locked.   | (b) (4), (b) (6)                           | 02 May 2021 05:17:29                         |
| User signature succeeded.   | Douglas Denham (b) (4)                     | 22 Apr 2021 15:51:45                         |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)                | 11 Feb 2021 19:24:56                         |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OTHER<br>ANALGESICS AND ANTIPYRETICS, ATC:<br>ANILIDES, PRODUCT: PARACETAMOL,<br>PRODUCTSYNONYM: TYLENOL - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 21 Dec 2020 21:33:42                         |
| 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)            | 21 Dec 2020 21:33:42                         |
| Data point term sent to Coder<br>Coding entries removed.  | System<br>Dawn Killian (b) (4)             | 21 Dec 2020 19:44:10<br>21 Dec 2020 19:43:13 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OTHER<br>ANALGESICS AND ANTIPYRETICS, ATC:<br>ANILIDES, PRODUCT: PARACETAMOL,<br>PRODUCTSYNONYM: TYLENOL - version<br>WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 01 Oct 2020 18:50:52                         |
| 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)            | 01 Oct 2020 18:50:52                         |
| Data point term sent to Coder<br>User entered 'Tylenol'   | System<br>(b) (4), (b) (6)                 | 01 Oct 2020 18:49:40<br>01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:34:27

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 05:17:29 |
| User signature succeeded. | Douglas Denham (b) (4)<br>(b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)                  | 11 Feb 2021 19:24:56 |
| User entered 'No (N)'     |                                   | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:34:27

[Indication](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 02 May 2021 05:17:29 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User closed query 'Per CDM: Please update the indication to reflect the location and type of PAIN as there is no record of FEVER/PAIN (EDIARY) in the eDiary during this timeframe. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).                   | (b) (4), (b) (6)       | 16 Apr 2021 09:48:01 |
| Query 'Per CDM: Please update the indication to reflect the location and type of PAIN as there is no record of FEVER/PAIN (EDIARY) in the eDiary during this timeframe. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'correct as is' (Site from DM). | Dawn Killian (b) (4)   | 13 Apr 2021 20:40:56 |
| User opened query 'Per CDM: Please update the indication to reflect the location and type of PAIN as there is no record of FEVER/PAIN (EDIARY) in the eDiary during this timeframe. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).                   | (b) (4), (b) (6)       | 26 Mar 2021 09:10:08 |
| DataPoint Verified.  | (b) (4), (b) (6)       | 11 Feb 2021 19:24:56 |
| User closed query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN (e.g. injection site pain, muscle pain, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).   | (b) (4), (b) (6)       | 29 Dec 2020 10:16:33 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:34:27

[Indication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.<br />' (Site from DM).                            | (b) (4), (b) (6)                | 29 Dec 2020 10:14:57 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.<br>' answered with 'did not meet AE criteria' (Site from DM). | Dawn Killian (b) (4)<br>(b) (4) | 21 Dec 2020 19:43:24 |
| Query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN (e.g. injection site pain, muscle pain, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.<br>' answered with 'this is edinary' (Site from DM).   | Dawn Killian (b) (4)<br>(b) (4) | 21 Dec 2020 19:43:18 |
| User entered 'FEVER/PAIN (edinary)' reason for change: Data Entry Error  | Dawn Killian (b) (4)<br>(b) (4) | 21 Dec 2020 19:43:13 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:34:27

[Indication](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of FEVER did not meet the AE reporting criteria.<br />' (Site from DM). | (b) (4), (b) (6) | 02 Dec 2020 10:14:00 |
| User opened query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN (e.g. injection site pain, muscle pain, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).   |                  | 02 Dec 2020 10:12:58 |
| User entered 'Fever/pain'   |                  | 01 Oct 2020 18:49:05 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:34:27**

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 05:17:29 |
| User signature succeeded. | Douglas Denham (b) (4)<br>(b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)                  | 11 Feb 2021 19:24:56 |
| User entered '500'        |                                   | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:34:27

[Dose unit](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 02 May 2021 05:17:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:24:56 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)       | 01 Oct 2020 18:49:05 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:34:27**

[If dose unit is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 02 May 2021 05:17:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:24:56 |
| User entered empty.       | (b) (4), (b) (6)       | 01 Oct 2020 18:49:05 |



US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:34:27

[Frequency](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)       | 02 May 2021 05:17:29 |
| User signature succeeded.      | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.            | (b) (4)                | 11 Feb 2021 19:24:56 |
| User entered 'once daily (QD)' | (b) (4), (b) (6)       | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:34:27

If frequency is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 02 May 2021 05:17:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:24:56 |
| User entered empty.       | (b) (4), (b) (6)       | 01 Oct 2020 18:49:05 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:34:27**

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 05:17:29 |
| User signature succeeded.  | Douglas Denham (b) (4)<br>(b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4), (b) (6)                  | 11 Feb 2021 19:24:56 |
| User entered 'Oral (ORAL)' |                                   | 01 Oct 2020 18:49:05 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:34:27**

If route of administration is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 02 May 2021 05:17:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:24:56 |
| User entered empty.       | (b) (4), (b) (6)       | 01 Oct 2020 18:49:05 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:34:27**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 02 May 2021 05:17:29 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4)                | 11 Feb 2021 19:24:56 |
| User entered '25 Sep 2020' | (b) (4), (b) (6)       | 01 Oct 2020 18:49:05 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:34:27**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 02 May 2021 05:17:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:24:56 |
| User entered '0'          | (b) (4), (b) (6)       | 01 Oct 2020 18:49:05 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:34:27**

[Ongoing?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 02 May 2021 05:17:29 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)                | 11 Feb 2021 19:24:56 |
| User entered 'No (N)'     | (b) (4), (b) (6)       | 01 Oct 2020 18:49:05 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:34:27**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 02 May 2021 05:17:29 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 11 Feb 2021 19:24:56 |
| User entered '25 Sep 2020' |                        | 01 Oct 2020 18:49:05 |



US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:34:27

[Was this medication taken for solicited event?](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                  | 02 May 2021 05:17:29 |
| User signature succeeded.  | Douglas Denham (b) (4)<br>(b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.  | (b) (4), (b) (6)                  | 20 Apr 2021 17:25:50 |
| User closed query 'Per CDM: As per previous query, please review if 'FEVER/PAIN' is considered as an unsolicited event per protocol. If yes, please update and record this condition in the AE eCRF else, provide clarification. Thank you. ' (Site from DM).<br>Query 'Per CDM: As per previous query, please review if 'FEVER/PAIN' is considered as an unsolicited event per protocol. If yes, please update and record this condition in the AE eCRF else, provide clarification. Thank you. ' answered with 'updated' (Site from DM). | (b) (4)                           | 16 Apr 2021 09:47:55 |
| DataPoint Un-verified.   | Dawn Killian (b) (4)<br>(b) (4)   | 13 Apr 2021 20:41:48 |
| User entered 'Yes (Y)' reason for change: Per Query Resolution   | Dawn Killian (b) (4)<br>(b) (4)   | 13 Apr 2021 20:40:08 |
| User opened query 'Per CDM: As per previous query please review if 'FEVER/PAIN' is considered as an unsolicited event per protocol. If yes, please update and record this condition in the AE eCRF else, provide clarification. Thank you. ' (Site from DM).   | (b) (4), (b) (6)                  | 26 Mar 2021 09:07:55 |
| User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER/PAIN (EDIARY) in the eDiary during this timeframe. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in the AE eCRF and update this field to No Else, provide clarification.' (Site from DM).  |                                   | 26 Mar 2021 09:07:55 |
| DataPoint Verified.  |                                   | 25 Mar 2021 21:03:15 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:34:27

Was this medication taken for solicited event?

| Audit  | User                      | Time (GMT)           |
|--|---------------------------|----------------------|
| Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER/PAIN (EDIARY) in the eDiary during this timeframe. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in the AE eCRF and update this field to No. Else, provide clarification.' answered with 'updated as per query' (Site from DM). DataPoint Un-verified. | Antonio Gutierrez (b) (4) | 24 Mar 2021 16:50:23 |
|  | Antonio Gutierrez (b) (4) | 24 Mar 2021 16:50:14 |
| User entered 'No (N)' reason for change: Per Query Resolution DataPoint Verified.  | Antonio Gutierrez (b) (4) | 24 Mar 2021 16:50:14 |
|  | (b) (4), (b) (6)          | 11 Feb 2021 19:24:56 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER/PAIN (EDIARY) in the eDiary during this timeframe. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in the AE eCRF and update this field to No Else, provide clarification.' (Site from DM). User entered 'Yes (Y)'                           |                           | 02 Feb 2021 03:56:17 |
|  |                           | 01 Oct 2020 18:49:05 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:34:27**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 05:17:29 |
| User entered 'I'  | System           | 01 Oct 2020 18:49:05 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 05:17:29 |
| User entered 'I'  | System           | 01 Oct 2020 18:49:05 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 05:17:29 |
| User entered '804 (804)' | System           | 01 Oct 2020 18:49:05 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

[Name of Medication](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 02 May 2021 05:16:56 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.  | (b) (4)                | 11 Feb 2021 19:29:47 |
| Query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' canceled (Site from DM).    | (b) (4), (b) (6)       | 16 Jan 2021 21:34:26 |
| User opened query 'Per DM CLR: This Conmed is given for the AE#1. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM). |                        | 16 Jan 2021 21:34:03 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: INTERMEDIATE-ACTING SULFONAMIDES, PRODUCT: SULFAMETHOXAZOLE - version WHODrug-Global-B3\202003.                            | Coder Import (b) (4)   | 09 Oct 2020 20:18:58 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.   | Coder Import (b) (4)   | 09 Oct 2020 20:18:58 |
| Data point term sent to Coder  | System                 | 09 Oct 2020 01:51:32 |
| User entered 'sulfamethoxazole'  | Kristy Trevino (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

[Prophylaxis](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 02 May 2021 05:16:56 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 11 Feb 2021 19:29:48 |
| User entered 'No (N)'     | Kristy Trevino (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

[Indication](#)

| Audit                                  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.                      | (b) (4), (b) (6)                  | 02 May 2021 05:16:56 |
| User signature succeeded.              | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                    | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:29:50 |
| User entered 'Urinary tract Infection' | Kristy Trevino (b) (4)<br>(b) (4) | 09 Oct 2020 01:50:39 |



US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

[Dose per administration](#)

| Audit   | User                                  | Time (GMT)           |
|---|---------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                      | 02 May 2021 05:16:56 |
| User signature succeeded.   | Douglas Denham (b) (4)<br>(b) (4)     | 22 Apr 2021 15:51:45 |
| User closed query 'Per source, Dose amount is 1. please review and reconcile.' (Site from CRA).             | (b) (4), (b) (6)                      | 25 Mar 2021 21:03:23 |
| DataPoint Verified.   |                                       | 25 Mar 2021 21:03:22 |
| Query 'Per source, Dose amount is 1. please review and reconcile.' answered with 'updated' (Site from CRA). | Victoria Hernandez (b) (4)<br>(b) (4) | 24 Mar 2021 16:34:09 |
| User entered '1' reason for change: Data Entry Error  | Victoria Hernandez (b) (4)<br>(b) (4) | 24 Mar 2021 16:34:02 |
| User opened query 'Per source, Dose amount is 1. please review and reconcile.' (Site from CRA).             | (b) (4), (b) (6)                      | 11 Feb 2021 19:29:01 |
| User entered 'UNK'  | Kristy Trevino (b) (4)<br>(b) (4)     | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

[Dose unit](#)

| Audit   | User                       | Time (GMT)           |
|---|----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)           | 02 May 2021 05:16:56 |
| User signature succeeded.   | Douglas Denham (b) (4)     | 22 Apr 2021 15:51:45 |
| User closed query 'Per source, Dose unit is tab. please review and reconcile.' (Site from CRA).             | (b) (4)                    |                      |
| DataPoint Verified.   | (b) (4), (b) (6)           | 25 Mar 2021 21:03:28 |
|   |                            | 25 Mar 2021 21:03:26 |
| Query 'Per source, Dose unit is tab. please review and reconcile.' answered with 'updated' (Site from CRA). | Victoria Hernandez (b) (4) | 24 Mar 2021 16:34:13 |
| User entered 'tablet (TABLET)' reason for change:   | (b) (4)                    |                      |
| Data Entry Error  | Victoria Hernandez (b) (4) | 24 Mar 2021 16:34:02 |
| User opened query 'Per source, Dose unit is tab. please review and reconcile.' (Site from CRA).             | (b) (4)                    |                      |
| User entered 'Other (OTHER)'  | (b) (4), (b) (6)           | 11 Feb 2021 19:29:30 |
|   | Kristy Trevino (b) (4)     | 09 Oct 2020 01:50:39 |
|   | (b) (4)                    |                      |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

If dose unit is Other, specify

| Audit  | User                       | Time (GMT)           |
|--|----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)           | 02 May 2021 05:16:56 |
| User signature succeeded.  | Douglas Denham (b) (4)     | 22 Apr 2021 15:51:45 |
| User closed query 'Per source, Dose unit is tab. please review and reconcile' (Site from CRA).             | (b) (4)                    |                      |
| DataPoint Verified.  | (b) (4), (b) (6)           | 25 Mar 2021 21:03:31 |
|  |                            | 25 Mar 2021 21:03:29 |
| Query 'Per source, Dose unit is tab. please review and reconcile' answered with 'updated' (Site from CRA). | Victoria Hernandez (b) (4) | 24 Mar 2021 16:34:18 |
| User entered empty; reason for change Data Entry Error   | (b) (4)                    |                      |
|  | Victoria Hernandez (b) (4) | 24 Mar 2021 16:34:02 |
| User opened query 'Per source, Dose unit is tab. please review and reconcile' (Site from CRA).             | (b) (4), (b) (6)           | 11 Feb 2021 19:31:03 |
| User entered 'Subject bottle does not state dose'  | Kristy Trevino (b) (4)     | 09 Oct 2020 01:50:39 |
|  | (b) (4)                    |                      |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

[Frequency](#)

| Audit                            | User                              | Time (GMT)           |
|----------------------------------|-----------------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)                  | 02 May 2021 05:16:56 |
| User signature succeeded.        | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:29:52 |
| User entered 'twice daily (BID)' | Kristy Trevino (b) (4)<br>(b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

[If frequency is Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 02 May 2021 05:16:56 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 11 Feb 2021 19:29:54 |
| User entered empty.       | Kristy Trevino (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

[Route of administration](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 02 May 2021 05:16:56 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 11 Feb 2021 19:29:58 |
| User entered 'Oral (ORAL)' | Kristy Trevino (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

If route of administration is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 05:16:56 |
| User signature succeeded. | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:30:21 |
| User entered empty.       | Kristy Trevino (b) (4)<br>(b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

Start date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 02 May 2021 05:16:56 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 11 Feb 2021 19:30:19 |
| User entered '16 Sep 2020' | Kristy Trevino (b) (4) | 09 Oct 2020 01:50:39 |



US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 05:16:56 |
| User signature succeeded. | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:30:18 |
| User entered '0'          | Kristy Trevino (b) (4)<br>(b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

[Ongoing?](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 02 May 2021 05:16:56 |
| User signature succeeded.                                 | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.                                       | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:30:16 |
| User entered 'No (N)' reason for change: Data Entry Error | Kevin Martinez (b) (4)<br>(b) (4) | 22 Oct 2020 15:53:02 |
| User entered 'Yes (Y)'                                    | Kristy Trevino (b) (4)<br>(b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                             | 02 May 2021 05:16:56 |
| User signature succeeded.                                      | Douglas Denham (b) (4)                       | 22 Apr 2021 15:51:45 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6)                  | 11 Feb 2021 19:30:14 |
| User entered '26 Sep 2020' reason for change: Data Entry Error | Kevin Martinez (b) (4)                       | 22 Oct 2020 15:53:02 |
| User entered empty.  | (b) (4)<br>Kristy Trevino (b) (4)<br>(b) (4) | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:34:27

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 02 May 2021 05:16:56 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 11 Feb 2021 19:30:12 |
| User entered 'No (N)'     | Kristy Trevino (b) (4) | 09 Oct 2020 01:50:39 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:34:27**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 05:16:56 |
| User entered '2'  | System           | 09 Oct 2020 01:50:39 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 05:16:56 |
| User entered 'I'  | System           | 09 Oct 2020 01:50:39 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 05:16:56 |
| User entered '804 (804)' | System           | 09 Oct 2020 01:50:39 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

[Name of Medication](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                  | 02 May 2021 05:17:23 |
| User signature succeeded.   | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:31:10 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)   | 22 Oct 2020 15:55:35 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)   | 22 Oct 2020 15:55:35 |
| Data point term sent to Coder   | System                            | 22 Oct 2020 15:54:31 |
| User entered 'acyclovir'  | Kevin Martinez (b) (4)<br>(b) (4) | 22 Oct 2020 15:54:28 |



US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

[Prophylaxis](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 05:17:23 |
| User signature succeeded. | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:31:12 |
| User entered 'No (N)'     | Kevin Martinez (b) (4)<br>(b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

[Indication](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 02 May 2021 05:17:23 |
| User signature succeeded.   | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.   | (b) (4)                |                      |
|   | (b) (4), (b) (6)       | 11 Feb 2021 19:31:14 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.<br>' (Site from DM).              |                        | 29 Jan 2021 09:31:05 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.<br>' answered with 'ae added' (Site from DM). |                        | 27 Jan 2021 14:51:19 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.<br>' (Site from DM).              |                        | 16 Jan 2021 21:35:26 |
| User entered 'Shingles'   | Kevin Martinez (b) (4) | 22 Oct 2020 15:54:28 |
|   | (b) (4)                |                      |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

[Dose per administration](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 05:17:23 |
| User signature succeeded. | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:31:16 |
| User entered '400'        | Kevin Martinez (b) (4)<br>(b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

[Dose unit](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 05:17:23 |
| User signature succeeded. | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:31:22 |
| User entered 'mg (mg)'    | Kevin Martinez (b) (4)<br>(b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

If dose unit is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 05:17:23 |
| User signature succeeded. | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:31:24 |
| User entered empty.       | Kevin Martinez (b) (4)<br>(b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

[Frequency](#)

| Audit                            | User                              | Time (GMT)           |
|----------------------------------|-----------------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)                  | 02 May 2021 05:17:23 |
| User signature succeeded.        | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:31:26 |
| User entered 'twice daily (BID)' | Kevin Martinez (b) (4)<br>(b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

[If frequency is Other, specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 05:17:23 |
| User signature succeeded. | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:31:27 |
| User entered empty.       | Kevin Martinez (b) (4)<br>(b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

[Route of administration](#)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 02 May 2021 05:17:23 |
| User signature succeeded.  | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:31:29 |
| User entered 'Oral (ORAL)' | Kevin Martinez (b) (4)<br>(b) (4) | 22 Oct 2020 15:54:28 |



US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

If route of administration is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 05:17:23 |
| User signature succeeded. | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:31:30 |
| User entered empty.       | Kevin Martinez (b) (4)<br>(b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

Start date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 02 May 2021 05:17:23 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 11 Feb 2021 19:31:32 |
| User entered '14 Sep 2020' | Kevin Martinez (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 05:17:23 |
| User signature succeeded. | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:31:33 |
| User entered '0'          | Kevin Martinez (b) (4)<br>(b) (4) | 22 Oct 2020 15:54:28 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:34:27**

[Ongoing?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 05:17:23 |
| User signature succeeded. | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:31:35 |
| User entered 'No (N)'     | Kevin Martinez (b) (4)<br>(b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 02 May 2021 05:17:23 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 11 Feb 2021 19:31:37 |
| User entered '24 Sep 2020' | Kevin Martinez (b) (4) | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:34:27

[Was this medication taken for solicited event?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 02 May 2021 05:17:23 |
| User signature succeeded. | Douglas Denham (b) (4)            | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)       | 11 Feb 2021 19:31:39 |
| User entered 'No (N)'     | Kevin Martinez (b) (4)<br>(b) (4) | 22 Oct 2020 15:54:28 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:34:27**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 05:17:23 |
| User entered '2'  | System           | 22 Oct 2020 15:54:28 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 05:17:23 |
| User entered 'I'  | System           | 22 Oct 2020 15:54:28 |



**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 05:17:23 |
| User entered '804 (804)' | System           | 22 Oct 2020 15:54:28 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:34:27

[Name of Medication](#)

| Audit   | User                            | Time (GMT)                                   |
|---|---------------------------------|--|
| User signature succeeded.   | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45                         |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: DRUGS<br>FOR TREATMENT OF BONE DISEASES, ATC:<br>DRUGS AFFECTING BONE STRUCTURE AND<br>MINERALIZATION, ATC: BISPHOSPHONATES,<br>PRODUCT: IBANDRONATE SODIUM,<br>PRODUCTSYNONYM: BONIVA - version<br>WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 21 Apr 2021 20:58:29                         |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)            | 21 Apr 2021 20:58:29                         |
| Data point term sent to Coder<br>Coding entries removed.  | System<br>(b) (4), (b) (6)      | 21 Apr 2021 20:58:11<br>21 Apr 2021 20:58:10 |
| DataPoint Verified.   | (b) (4), (b) (6)                | 12 Apr 2021 17:20:39                         |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: DRUGS<br>FOR TREATMENT OF BONE DISEASES, ATC:<br>DRUGS AFFECTING BONE STRUCTURE AND<br>MINERALIZATION, ATC: BISPHOSPHONATES,<br>PRODUCT: IBANDRONATE SODIUM,<br>PRODUCTSYNONYM: BONIVA - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)            | 25 Mar 2021 16:03:31                         |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)            | 25 Mar 2021 16:03:31                         |
| Data point term sent to Coder<br>User entered 'boniva'  | System<br>Gerardo Pena (b) (4)  | 25 Mar 2021 15:33:00<br>25 Mar 2021 15:32:51 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:34:27

[Prophylaxis](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 12 Apr 2021 17:20:39 |
| User entered 'No (N)'     | Gerardo Pena (b) (4)<br>(b) (4) | 25 Mar 2021 15:32:51 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:34:27

[Indication](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)       | 23 Apr 2021 13:38:09 |
| User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.<br>' (Site from DM).             |                        | 23 Apr 2021 06:08:02 |
| User signature succeeded.  | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.<br>' answered with 'Updated' (Site from DM). | (b) (4), (b) (6)       | 21 Apr 2021 21:00:26 |
| DataPoint Un-verified.   |                        | 21 Apr 2021 20:58:10 |
| User entered 'OSTEOPENIA' reason for change:   |                        | 21 Apr 2021 20:58:10 |
| Data Entry Error   |                        |                      |
| DataPoint Verified.  |                        | 12 Apr 2021 17:20:39 |
| User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.<br>' (Site from DM).             |                        | 06 Apr 2021 09:51:18 |
| User entered 'osteoporosis'  | Gerardo Pena (b) (4)   | 25 Mar 2021 15:32:51 |
|  | (b) (4)                |                      |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:34:27

[Dose per administration](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 12 Apr 2021 17:20:39 |
| User entered '150'        | Gerardo Pena (b) (4)<br>(b) (4) | 25 Mar 2021 15:32:51 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:34:27

[Dose unit](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 12 Apr 2021 17:20:39 |
| User entered 'mg (mg)'    | Gerardo Pena (b) (4)<br>(b) (4) | 25 Mar 2021 15:32:51 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:34:27**

If dose unit is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 12 Apr 2021 17:20:39 |
| User entered empty.       | Gerardo Pena (b) (4)<br>(b) (4) | 25 Mar 2021 15:32:51 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:34:27

[Frequency](#)

| Audit                           | User                            | Time (GMT)           |
|---------------------------------|---------------------------------|----------------------|
| User signature succeeded.       | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.             | (b) (4)<br>(b) (4), (b) (6)     | 12 Apr 2021 17:20:39 |
| User entered 'every month (QM)' | Gerardo Pena (b) (4)<br>(b) (4) | 25 Mar 2021 15:32:51 |



US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:34:27

If frequency is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 12 Apr 2021 17:20:39 |
| User entered empty.       | Gerardo Pena (b) (4)<br>(b) (4) | 25 Mar 2021 15:32:51 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:34:27

[Route of administration](#)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)     | 12 Apr 2021 17:20:39 |
| User entered 'Oral (ORAL)' | Gerardo Pena (b) (4)<br>(b) (4) | 25 Mar 2021 15:32:51 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:34:27**

If route of administration is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 12 Apr 2021 17:20:39 |
| User entered empty.       | Gerardo Pena (b) (4)<br>(b) (4) | 25 Mar 2021 15:32:51 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:34:27

Start date (dd MMM yyyy)

| Audit                      | User                            | Time (GMT)           |
|----------------------------|---------------------------------|----------------------|
| User signature succeeded.  | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)     | 12 Apr 2021 17:20:39 |
| User entered '19 Mar 2021' | Gerardo Pena (b) (4)<br>(b) (4) | 25 Mar 2021 15:32:51 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:34:27

[Start date completely unknown](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 12 Apr 2021 17:20:39 |
| User entered '0'          | Gerardo Pena (b) (4)<br>(b) (4) | 25 Mar 2021 15:32:51 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:34:27

[Ongoing?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 12 Apr 2021 17:20:39 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)<br>(b) (4) | 25 Mar 2021 15:32:51 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:34:27

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 12 Apr 2021 17:20:39 |
| User entered empty.       | Gerardo Pena (b) (4)<br>(b) (4) | 25 Mar 2021 15:32:51 |

US3292324

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:34:27

[Was this medication taken for solicited event?](#)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)          | 22 Apr 2021 15:51:45 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 12 Apr 2021 17:20:39 |
| User entered 'No (N)'     | Gerardo Pena (b) (4)<br>(b) (4) | 25 Mar 2021 15:32:51 |



**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:34:27**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'l' | System | 25 Mar 2021 15:32:51 |

**US3292324**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 25 Mar 2021 15:32:51 |

US3292324

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:34:27**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '802 (802)' | System | 25 Mar 2021 15:32:51 |

US3292324

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:34:27

[Were any concomitant procedures performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 May 2021 05:13:34 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4), (b) (6)       | 11 Feb 2021 19:11:44 |
| User entered 'Yes (Y)'    | Gerardo Pena (b) (4)   | 23 Dec 2020 19:58:53 |

US3292324

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:34:27

Procedure/Surgery date (*dd MMM yyyy*)

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 11 Feb 2021 19:11:59 |
| User entered '4 Nov 2020' | Gerardo Pena (b) (4)<br>(b) (4) | 23 Dec 2020 19:59:50 |

US3292324

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:34:27

[Procedure/Surgery](#)

| Audit                             | User                            | Time (GMT)           |
|-----------------------------------|---------------------------------|----------------------|
| User signature succeeded.         | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| DataPoint Verified.               | (b) (4)<br>(b) (4), (b) (6)     | 11 Feb 2021 19:11:59 |
| User entered 'Right femur repair' | Gerardo Pena (b) (4)<br>(b) (4) | 23 Dec 2020 19:59:50 |

US3292324

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:34:27

[Indication](#)

| Audit                             | User                            | Time (GMT)           |
|-----------------------------------|---------------------------------|----------------------|
| User signature succeeded.         | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| DataPoint Verified.               | (b) (4)<br>(b) (4), (b) (6)     | 11 Feb 2021 19:11:59 |
| User entered 'Adverse Event (AE)' | Gerardo Pena (b) (4)<br>(b) (4) | 23 Dec 2020 19:59:50 |

US3292324

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:34:27

If indication is Other, specify

| Audit                     | User                            | Time (GMT)           |
|---------------------------|---------------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)          | 23 Feb 2021 14:15:51 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)     | 11 Feb 2021 19:11:59 |
| User entered empty.       | Gerardo Pena (b) (4)<br>(b) (4) | 23 Dec 2020 19:59:50 |



**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.                             | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered<br>'USA-US072-2020-MRNA-1273-P301000008' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |



US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Douglas'    | System                      | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Denham'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Street](#)

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.            | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                 | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '7940 Floyd Curl Drive' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: City](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.       | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'San Antonio' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '78229'      | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:29:29 |
| User entered 'US'         | System                      | 04 Nov 2020 18:49:26 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '6'          | System                 | 21 Apr 2021 21:13:34 |
| User entered '5'          | System                 | 21 Apr 2021 20:52:11 |
| User entered '4'          | System                 | 25 Mar 2021 15:40:19 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
|                           | (b) (4)                |                      |
| User entered '3'          | System                 | 21 Jan 2021 15:29:50 |
| User entered '2'          | System                 | 11 Dec 2020 13:51:46 |
| User entered '1'          | System                 | 04 Nov 2020 18:49:26 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.                             | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered<br>'USA-US072-2020-MRNA-1273-P301000008' | System                      | 04 Nov 2020 18:48:49 |



**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Douglas'    | System                      | 04 Nov 2020 18:48:49 |



US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Denham'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Street](#)

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.            | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                 | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '7940 Floyd Curl Drive' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: City](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.       | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'San Antonio' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '78229'      | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:29:29 |
| User entered 'US'         | System                      | 04 Nov 2020 18:49:26 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '6'          | System                 | 21 Apr 2021 21:13:34 |
| User entered '5'          | System                 | 21 Apr 2021 20:52:11 |
| User entered '4'          | System                 | 25 Mar 2021 15:40:19 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
|                           | (b) (4)                |                      |
| User entered '3'          | System                 | 21 Jan 2021 15:29:50 |
| User entered '2'          | System                 | 11 Dec 2020 13:51:46 |
| User entered '1'          | System                 | 04 Nov 2020 18:49:26 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:34:27**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 09 Apr 2021 18:42:44 |
| User signature succeeded.        | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '04/Nov/2020 18:49' | (b) (4)<br>System      | 04 Nov 2020 18:49:26 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:34:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)                  | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)<br>(b) (4) | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4), (b) (6)                  | 21 Jan 2021 15:29:29 |
| User entered 'l'          |                                   | 04 Nov 2020 18:49:26 |



**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.                             | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered<br>'USA-US072-2020-MRNA-1273-P301000008' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |



US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Douglas'    | System                      | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Denham'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Street](#)

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.            | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                 | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '7940 Floyd Curl Drive' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: City](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.       | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'San Antonio' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '78229'      | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:29:29 |
| User entered 'US'         | System                      | 04 Nov 2020 18:49:26 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '6'          | System                 | 21 Apr 2021 21:13:34 |
| User entered '5'          | System                 | 21 Apr 2021 20:52:11 |
| User entered '4'          | System                 | 25 Mar 2021 15:40:19 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
|                           | (b) (4)                |                      |
| User entered '3'          | System                 | 21 Jan 2021 15:29:50 |
| User entered '2'          | System                 | 11 Dec 2020 13:51:46 |
| User entered '1'          | System                 | 04 Nov 2020 18:49:26 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:34:27**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 09 Apr 2021 18:42:44 |
| User signature succeeded.        | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '11/Dec/2020 05:51' | (b) (4)<br>System      | 11 Dec 2020 13:51:46 |



US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:34:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)                | 21 Jan 2021 15:29:29 |
| User entered 'l'          | (b) (4), (b) (6)       | 11 Dec 2020 13:51:46 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.                             | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered<br>'USA-US072-2020-MRNA-1273-P301000008' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |



**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Douglas'    | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Denham'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Street](#)

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.            | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                 | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '7940 Floyd Curl Drive' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: City](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.       | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'San Antonio' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '78229'      | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:29:29 |
| User entered 'US'         | System                      | 04 Nov 2020 18:49:26 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '6'          | System                 | 21 Apr 2021 21:13:34 |
| User entered '5'          | System                 | 21 Apr 2021 20:52:11 |
| User entered '4'          | System                 | 25 Mar 2021 15:40:19 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
|                           | (b) (4)                |                      |
| User entered '3'          | System                 | 21 Jan 2021 15:29:50 |
| User entered '2'          | System                 | 11 Dec 2020 13:51:46 |
| User entered '1'          | System                 | 04 Nov 2020 18:49:26 |



**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:34:27**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 09 Apr 2021 18:42:44 |
| User signature succeeded.        | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered '21/Jan/2021 15:29' | (b) (4)<br>System      | 21 Jan 2021 15:29:50 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:34:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)       | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
| User entered 'I'          | (b) (4), (b) (6)       | 21 Jan 2021 15:29:50 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.                             | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered<br>'USA-US072-2020-MRNA-1273-P301000008' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |



**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Douglas'    | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Denham'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Street](#)

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.            | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                 | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '7940 Floyd Curl Drive' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: City](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.       | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'San Antonio' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '78229'      | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:29:29 |
| User entered 'US'         | System                      | 04 Nov 2020 18:49:26 |



US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '6'          | System                 | 21 Apr 2021 21:13:34 |
| User entered '5'          | System                 | 21 Apr 2021 20:52:11 |
| User entered '4'          | System                 | 25 Mar 2021 15:40:19 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
|                           | (b) (4)                |                      |
| User entered '3'          | System                 | 21 Jan 2021 15:29:50 |
| User entered '2'          | System                 | 11 Dec 2020 13:51:46 |
| User entered '1'          | System                 | 04 Nov 2020 18:49:26 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:34:27**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Douglas Denham (b) (4)      | 16 Apr 2021 14:42:31 |
| DataPoint Verified.              | (b) (4)<br>(b) (4), (b) (6) | 09 Apr 2021 18:42:44 |
| User entered '25/Mar/2021 08:40' | System                      | 25 Mar 2021 15:40:19 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:34:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Douglas Denham (b) (4)      | 16 Apr 2021 14:42:31 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 09 Apr 2021 18:42:44 |
| User entered 'I'          |                             | 25 Mar 2021 15:40:19 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.                             | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered<br>'USA-US072-2020-MRNA-1273-P301000008' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |



**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Douglas'    | System                      | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Denham'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Street](#)

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.            | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                 | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '7940 Floyd Curl Drive' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: City](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.       | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'San Antonio' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '78229'      | System                      | 04 Nov 2020 18:48:49 |



**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:29:29 |
| User entered 'US'         | System                      | 04 Nov 2020 18:49:26 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '6'          | System                 | 21 Apr 2021 21:13:34 |
| User entered '5'          | System                 | 21 Apr 2021 20:52:11 |
| User entered '4'          | System                 | 25 Mar 2021 15:40:19 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
|                           | (b) (4)                |                      |
| User entered '3'          | System                 | 21 Jan 2021 15:29:50 |
| User entered '2'          | System                 | 11 Dec 2020 13:51:46 |
| User entered '1'          | System                 | 04 Nov 2020 18:49:26 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 16:34:27**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 22 Apr 2021 22:25:51 |
| User signature succeeded.        | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered '21/Apr/2021 16:52' | (b) (4)<br>System      | 21 Apr 2021 20:52:11 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:34:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)       | 22 Apr 2021 22:25:51 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered 'I'          | (b) (4), (b) (6)       | 21 Apr 2021 20:52:11 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.                             | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered<br>'USA-US072-2020-MRNA-1273-P301000008' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |



**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Yes (Y)'    | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'No (N)'     | System                      | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Douglas'    | System                      | 04 Nov 2020 18:48:49 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'Denham'     | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Street](#)

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                  | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.            | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.                 | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '7940 Floyd Curl Drive' | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: City](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded.  | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.       | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered 'San Antonio' | System                      | 04 Nov 2020 18:48:49 |



**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 04 Nov 2020 18:49:19 |
| User entered '78229'      | System                      | 04 Nov 2020 18:48:49 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:34:27**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 09 Apr 2021 18:42:44 |
| User signature succeeded. | Douglas Denham (b) (4)      | 23 Feb 2021 14:15:51 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Jan 2021 15:29:29 |
| User entered 'US'         | System                      | 04 Nov 2020 18:49:26 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 16:34:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '6'          | System                 | 21 Apr 2021 21:13:34 |
| User entered '5'          | System                 | 21 Apr 2021 20:52:11 |
| User entered '4'          | System                 | 25 Mar 2021 15:40:19 |
| User signature succeeded. | Douglas Denham (b) (4) | 23 Feb 2021 14:15:51 |
|                           | (b) (4)                |                      |
| User entered '3'          | System                 | 21 Jan 2021 15:29:50 |
| User entered '2'          | System                 | 11 Dec 2020 13:51:46 |
| User entered '1'          | System                 | 04 Nov 2020 18:49:26 |

**US3292324**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000008**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 16:34:27**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 22 Apr 2021 22:25:54 |
| User signature succeeded.        | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered '21/Apr/2021 17:13' | (b) (4)<br>System      | 21 Apr 2021 21:13:34 |

US3292324

Folder: SAE USA-US072-2020-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:34:27

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)       | 22 Apr 2021 22:25:54 |
| User signature succeeded. | Douglas Denham (b) (4) | 22 Apr 2021 15:51:45 |
| User entered 'I'          | (b) (4), (b) (6)       | 21 Apr 2021 21:13:34 |