

US3712308 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:23:35

All time stamps listed in this document are displayed in GMT

US3712308

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 00:44:21

Generated On: 12 Aug 2021 13:23:35

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Participant ID

US3712308

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

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US3712308

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 23 OCT 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | SCRN                                    |

US3712308

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

|   |  |
|---|--|
| Date of Birth (MMM yyyy)                  | (b) (6) 1973   |
| Age                                       | 46   |
| Age Units                                 | YEARS  |
| Age (Derived)                             | 47   |
| Sex                                       | Female <input checked="" type="radio"/><br>Male <input type="radio"/>  |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |  |
| White                                     | True   |
| Black                                     | False  |
| Asian                                     | False  |
| American Indian or Alaska Native          | False  |
| Native Hawaiian or other Pacific Islander | False  |
| Other                                     | False  |
| If race is Other, specify _____           |  |
| Unknown                                   | False  |
| Not reported                              | False  |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 20:45:02

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|   |  |
|---|--|
| Date of Informed Consent ( <i>dd MMM yyyy</i> ) | 23 OCT 2020  |
| Month and Year of Informed Consent (derived)    | OCT 2020   |
| Year of Informed Consent (derived)              | 2020   |
| Protocol Version                                | Amendment 1 <input type="radio"/><br>Amendment 2 <input type="radio"/><br>Amendment 3 <input type="radio"/><br>Amendment 4 <input checked="" 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) 13 Feb 2021 20:45:02

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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) 13 Feb 2021 20:45:03

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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) 13 Feb 2021 20:45:02

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|   |  |
|---|--|
| Condition   | ALLERGY TO LEVAQUIN  |
| Start date (dd MMM yyyy)                                | UN UNK 2006  |
| 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 2006   |
| Start Year (derived)                                    | 2006   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 20:45:02

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|   |  |
|---|--|
| Condition   | WISDOM TEETH IMPACTION   |
| Start date (dd MMM yyyy)                          | UN UNK 1993  |
| 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 1993  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 1993   |
| Start Year (derived)                              | 1993   |
| Stop Month and Year (derived)                     | JAN 1993   |
| Stop Year (derived)                               | 1993   |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 20:45:02

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|   |  |
|---|--|
| Condition   | WISDOM TEETH EXTRACTION  |
| Start date (dd MMM yyyy)                          | UN UNK 1993  |
| 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 1993  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 1993   |
| Start Year (derived)                              | 1993   |
| Stop Month and Year (derived)                     | JAN 1993   |
| Stop Year (derived)                               | 1993   |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 20:45:02

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|   |  |
|---|--|
| Condition   | SEASONAL ALLERGIES   |
| Start date (dd MMM yyyy)                                | UN UNK 2008  |
| 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 2008   |
| Start Year (derived)                                    | 2008   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 20:45:02

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|   |  |
|---|--|
| Condition   | HYPERTENSION   |
| Start date (dd MMM yyyy)                                | UN UNK 2008  |
| 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 2008   |
| Start Year (derived)                                    | 2008   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 20:45:02

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|   |  |
|---|--|
| Condition   | OCCASIONAL BRONCHITIS  |
| 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 (7)

Data signed: (b) (4) 13 Feb 2021 20:45:02

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|   |  |
|---|--|
| Condition   | BRONCHITIS INDUCED<br>ASTHMA                                     |
| 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 (8)

Data signed: (b) (4) 13 Feb 2021 20:45:02

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|   |  |
|---|--|
| Condition   | HYPOTHYROIDISM   |
| 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 (9)

Data signed: (b) (4) 13 Feb 2021 20:45:02

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|   |  |
|---|--|
| Condition   | ACID REFLUX  |
| Start date (dd MMM yyyy)                                | UN UNK 2008  |
| 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 2008   |
| Start Year (derived)                                    | 2008   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 20:45:02

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|   |  |
|---|--|
| Condition   | LEFT ANKLE 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 (11)

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

|   |  |
|---|--|
| Condition   | LEFT ANKLE REPAIR  |
| 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 (12)

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

|   |  |
|---|--|
| Condition   | MIGRAINES  |
| Start date (dd MMM yyyy)                                | UN UNK 1998  |
| 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 1998   |
| Start Year (derived)                                    | 1998   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

|   |  |
|---|--|
| Condition   | ANXIETY  |
| 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 (14)

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

|   |  |
|---|--|
| Condition   | BREAST IMPLANTS PLACED   |
| Start date (dd MMM yyyy)                          | UN UNK 2006  |
| 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 2006  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2006   |
| Start Year (derived)                              | 2006   |
| Stop Month and Year (derived)                     | JAN 2006   |
| Stop Year (derived)                               | 2006   |

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

|   |  |
|---|--|
| Condition   | OBESITY  |
| Start date (dd MMM yyyy)                          | UN UNK 2019  |
| 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 2019   |
| Start Year (derived)                              | 2019   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 17:16:00

Generated On: 12 Aug 2021 13:23:35

|                                     |                                      |
|-------------------------------------|--------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/> |
|                                     | No <input type="radio"/>             |
| Date of assessment (dd MMM yyyy)    | 23 OCT 2020                          |
| Time of assessment (00:00-23:59)    | 14:15 (24 HR)                        |
| Vital Signs Date and Time (derived) | 23 OCT 2020 14:15                    |
| Height (xxx.x)                      | 161.5 cm                             |
| Weight (xxx.x)                      | 89.1 kg                              |
| BMI (xxx.x)                         | 34.16116 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) 13 Feb 2021 20:45:03

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 20:45:02

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Date of assessment (dd MMM yyyy) 23 OCT 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 20:45:03

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|                                     |   |
|-------------------------------------|---|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 23 OCT 2020                               |
| Test performed                      | Urine <input checked="" type="radio"/>    |
|                                     | Serum <input type="radio"/>               |
| Result                              | Positive <input type="radio"/>            |
|                                     | Negative <input checked="" type="radio"/> |
| Was FSH sample collected?           | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Collection date                     |   |
| Collection time                     |   |
| Collection date and time (derived)  |   |

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 20:45:03

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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**

FUNERAL, RESTAURANTS AND BARS

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**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) 13 Feb 2021 20:45:03

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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) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 23 OCT 2020 |
|--------------------------|-------------|

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

|            |        |
|------------|--------|
| Folder OID | VISIT1 |
|------------|--------|

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 20:45:32

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What was the date of randomization? (dd MMM yyyy) 23 OCT 2020

What was the participant's randomization number? 118021

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) 20 Feb 2021 17:16:00

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 17:16:00

Generated On: 12 Aug 2021 13:23:35

|                                     |  |
|-------------------------------------|--|
| 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)    | 23 OCT 2020  |
| Time of assessment (00:00-23:59)    | 14:15 (24 HR)  |
| Vital Signs Date and Time (derived) | 23 OCT 2020 14:15  |
| Temperature (xxx.x)                 | 37.4 C   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 60 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 125 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 79 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 17:16:00

Generated On: 12 Aug 2021 13:23:35

|                                     |  |
|-------------------------------------|--|
| 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)    | 23 OCT 2020  |
| Time of assessment (00:00-23:59)    | 17:57 (24 HR)  |
| Vital Signs Date and Time (derived) | 23 OCT 2020 17:57  |
| Temperature (xxx.x)                 | 37.0 C   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 68 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 129 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 87 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3712308

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

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.*

US3712308

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

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

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

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

US3712308

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

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) 23 OCT 2020

What was the treatment time? (00:00-23:59) 17:27 (24 HR)

Treatment Date and Time (derived) 23 OCT 2020 17:27

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

US3712308

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 23 OCT 2020                          |
| Collection time (00:00-23:59)      | 14:44 (24 HR)                        |
| Collection date and time (derived) | 23 OCT 2020 14:44                    |

US3712308

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 23:53:27

Generated On: 12 Aug 2021 13:23:35

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 23 OCT 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 14:46                           | 23 OCT 2020 14:46                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3712308

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**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

98.6 °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

23 OCT 2020 18:16

PC Open Date & Time

23 OCT 2020 17:47

PC Close Date & Time

23 OCT 2020 20:17

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**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 98.2 °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        | 23 OCT 2020 22:32 |
| PC Open Date & Time  | 23 OCT 2020 21:12 |
| PC Close Date & Time | 24 OCT 2020 11:59 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**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

98.4 °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

24 OCT 2020 12:18

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 17:10

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 12:20

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 12:30

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**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

98.9 °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

28 OCT 2020 14:57

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 13:14

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**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

23 OCT 2020 18:18

PC Open Date & Time

23 OCT 2020 17:47

PC Close Date & Time

23 OCT 2020 20:17

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**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

23 OCT 2020 22:32

PC Open Date & Time

23 OCT 2020 21:12

PC Close Date & Time

24 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**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

24 OCT 2020 12:18

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**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

25 OCT 2020 16:43

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**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

26 OCT 2020 12:14

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**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

27 OCT 2020 12:27

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**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

28 OCT 2020 14:58

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**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

29 OCT 2020 13:12

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**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 ☐

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 23 OCT 2020 18:18 |
| PC Open Date & Time  | 23 OCT 2020 17:47 |
| PC Close Date & Time | 23 OCT 2020 20:17 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**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 ☐

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 23 OCT 2020 22:33 |
| PC Open Date & Time  | 23 OCT 2020 21:12 |
| PC Close Date & Time | 24 OCT 2020 11:59 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

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)

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 24 OCT 2020 12:19 |
| PC Open Date & Time          | 24 OCT 2020 12:00 |
| PC Close Date & Time         | 25 OCT 2020 11:59 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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)

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 25 OCT 2020 16:43 |
| PC Open Date & Time          | 25 OCT 2020 12:00 |
| PC Close Date & Time         | 26 OCT 2020 11:59 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 26 OCT 2020 12:15 |
| PC Open Date & Time          | 26 OCT 2020 12:00 |
| PC Close Date & Time         | 27 OCT 2020 11:59 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

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

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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)

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 28 OCT 2020 14:58 |
| PC Open Date & Time          | 28 OCT 2020 12:00 |
| PC Close Date & Time         | 29 OCT 2020 11:59 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 29 OCT 2020 13:12 |
| PC Open Date & Time          | 29 OCT 2020 12:00 |
| PC Close Date & Time         | 30 OCT 2020 11:59 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 30 OCT 2020 15:05

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp 31 OCT 2020 14:20

PC Open Date & Time 31 OCT 2020 12:00

PC Close Date & Time 01 NOV 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 NOV 2020 13:32

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 NOV 2020 12:15

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 12

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 NOV 2020 12:10

PC Open Date & Time

03 NOV 2020 12:00

PC Close Date & Time

04 NOV 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 13

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 NOV 2020 12:00

PC Close Date & Time

05 NOV 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(14)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 14

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 NOV 2020 12:00

PC Close Date & Time

06 NOV 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time Stamp

30 OCT 2020 15:05

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 31 OCT 2020 14:21

PC Open Date & Time 31 OCT 2020 12:00

PC Close Date & Time 01 NOV 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

01 NOV 2020 13:32

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 30 OCT 2020 15:05

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily activity ☐

PC Time stamp 31 OCT 2020 14:21

PC Open Date & Time 31 OCT 2020 12:00

PC Close Date & Time 01 NOV 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 01 NOV 2020 13:32

PC Open Date & Time 01 NOV 2020 12:00

PC Close Date & Time 02 NOV 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 02 NOV 2020 12:15

PC Open Date & Time 02 NOV 2020 12:00

PC Close Date & Time 03 NOV 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 12 Aug 2021 13:23:35

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

---

PC Time stamp 30 OCT 2020 15:06

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

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US3712308

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 8

Select one response below to indicate the level of your

**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 ☐

PC Time stamp 30 OCT 2020 15:06

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:23:35

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 8  |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 30 OCT 2020 15:06  |
| PC Open Date & Time   | 30 OCT 2020 12:00  |
| PC Close Date & Time  | 31 OCT 2020 11:59  |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:23:35

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 9  |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 31 OCT 2020 14:21  |
| PC Open Date & Time   | 31 OCT 2020 12:00  |
| PC Close Date & Time  | 01 NOV 2020 11:59  |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 12 Aug 2021 13:23:35

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 10   |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 01 NOV 2020 13:32  |
| PC Open Date & Time   | 01 NOV 2020 12:00  |
| PC Close Date & Time  | 02 NOV 2020 11:59  |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 12 Aug 2021 13:23:35

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 11   |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 02 NOV 2020 12:15  |
| PC Open Date & Time   | 02 NOV 2020 12:00  |
| PC Close Date & Time  | 03 NOV 2020 11:59  |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 12 Aug 2021 13:23:35

|   |                              |
|---|------------------------------|
| <b>TIMEPOINT</b>  | DAY 13                       |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input type="checkbox"/>  |
|   | Yes <input type="checkbox"/> |
| PC Time stamp   |                              |
| PC Open Date & Time   | 04 NOV 2020 12:00            |
| PC Close Date & Time  | 05 NOV 2020 11:59            |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 12 Aug 2021 13:23:35

|   |                              |
|---|------------------------------|
| <b>TIMEPOINT</b>  | DAY 14                       |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input type="checkbox"/>  |
|   | Yes <input type="checkbox"/> |
| PC Time stamp   |                              |
| PC Open Date & Time   | 05 NOV 2020 12:00            |
| PC Close Date & Time  | 06 NOV 2020 11:59            |

US3712308

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3712308

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712308

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 06 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3712308

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712308

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3712308

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712308

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 23 NOV 2020 |
|--------------------------|-------------|

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

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

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

|                                     |   |
|-------------------------------------|---|
| 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)    | 23 NOV 2020                               |
| Time of assessment (00:00-23:59)    | 07:25 (24 HR)                             |
| Vital Signs Date and Time (derived) | 23 NOV 2020 07:25                         |
| 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)                         | 78 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 20 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 125 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 91 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

|                                     |   |
|-------------------------------------|---|
| 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)    | 23 NOV 2020                                   |
| Time of assessment (00:00-23:59)    | 10:06 (24 HR)                                 |
| Vital Signs Date and Time (derived) | 23 NOV 2020 10:06                             |
| Temperature (xxx.x)                 | 36.9 C  |
| Route of measurement                | Oral <input checked="" type="checkbox"/>      |
|                                     | Axillary <input type="checkbox"/>             |
|                                     | Other <input type="checkbox"/>                |
| If Other, specify                   |   |
| Pulse (xxx)                         | 70 beats/min                                  |
| Pulse units                         | BPM   |
| Respiratory Rate (xxx)              | 16 breaths/min                                |
| Respiratory Rate units              | BREATHS/MIN                                   |
| Systolic Blood Pressure (xxx)       | 140 mmHg                                      |
| Systolic Blood Pressure units       | MMHG  |
| Diastolic Blood Pressure (xxx)      | 92 mmHg                                       |
| Diastolic Blood Pressure units      | MMHG  |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

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.*

US3712308

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

|                                     |   |
|-------------------------------------|---|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 23 NOV 2020                               |
| Test performed                      | Urine <input checked="" type="radio"/>    |
|                                     | Serum <input type="radio"/>               |
| Result                              | Positive <input type="radio"/>            |
|                                     | Negative <input checked="" type="radio"/> |
| Was FSH sample collected?           | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Collection date                     |   |
| Collection time                     |   |
| Collection date and time (derived)  |   |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

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) 23 NOV 2020

What was the treatment time? (00:00-23:59) 09:31 (24 HR)

Treatment Date and Time (derived) 23 NOV 2020 09:31

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

US3712308

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 NOV 2020

Collection time (00:00-23:59)

07:48 (24 HR)

Collection date and time (derived)

23 NOV 2020 07:48

US3712308

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Mar 2021 23:53:27

Generated On: 12 Aug 2021 13:23:35

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 23 NOV 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 07:53                           | 23 NOV 2020 07:53                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 NOV 2020 10:16

PC Open Date & Time

23 NOV 2020 09:51

PC Close Date & Time

23 NOV 2020 12:21

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

23 NOV 2020 13:16

PC Close Date & Time

24 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

24 NOV 2020 23:33

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**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 ☒

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 26 NOV 2020 23:34

PC Open Date & Time 26 NOV 2020 12:00

PC Close Date & Time 27 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 NOV 2020 12:00

PC Close Date & Time

28 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.8 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

28 NOV 2020 12:37

---

PC Open Date & Time

28 NOV 2020 12:00

---

PC Close Date & Time

29 NOV 2020 11:59

---

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**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

29 NOV 2020 17:33

PC Open Date & Time

29 NOV 2020 12:00

PC Close Date & Time

30 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**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

23 NOV 2020 10:16

PC Open Date & Time

23 NOV 2020 09:51

PC Close Date & Time

23 NOV 2020 12:21

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

23 NOV 2020 13:16

PC Close Date & Time

24 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**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

24 NOV 2020 23:32

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**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

26 NOV 2020 23:34

PC Open Date & Time

26 NOV 2020 12:00

PC Close Date & Time

27 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**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

27 NOV 2020 18:08

PC Open Date & Time

27 NOV 2020 12:00

PC Close Date & Time

28 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**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

28 NOV 2020 12:37

PC Open Date & Time

28 NOV 2020 12:00

PC Close Date & Time

29 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**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

29 NOV 2020 17:32

PC Open Date & Time

29 NOV 2020 12:00

PC Close Date & Time

30 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**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 ☐

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 23 NOV 2020 10:16 |
| PC Open Date & Time  | 23 NOV 2020 09:51 |
| PC Close Date & Time | 23 NOV 2020 12:21 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**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 ☐

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

23 NOV 2020 13:16

PC Close Date & Time

24 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**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 ☒

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 24 NOV 2020 23:32 |
| PC Open Date & Time          | 24 NOV 2020 12:00 |
| PC Close Date & Time         | 25 NOV 2020 11:59 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

Yes ☐

PC Time stamp

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**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 ☒

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 26 NOV 2020 23:34 |
| PC Open Date & Time          | 26 NOV 2020 12:00 |
| PC Close Date & Time         | 27 NOV 2020 11:59 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

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)

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 27 NOV 2020 18:08 |
| PC Open Date & Time          | 27 NOV 2020 12:00 |
| PC Close Date & Time         | 28 NOV 2020 11:59 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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 ☒

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 28 NOV 2020 12:37 |
| PC Open Date & Time          | 28 NOV 2020 12:00 |
| PC Close Date & Time         | 29 NOV 2020 11:59 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**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 ☒

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 29 NOV 2020 17:32 |
| PC Open Date & Time          | 29 NOV 2020 12:00 |
| PC Close Date & Time         | 30 NOV 2020 11:59 |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 30 NOV 2020 16:17

PC Open Date & Time 30 NOV 2020 12:00

PC Close Date & Time 01 DEC 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 02 DEC 2020 00:31

PC Open Date & Time 01 DEC 2020 12:00

PC Close Date & Time 02 DEC 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 02 DEC 2020 20:09

PC Open Date & Time 02 DEC 2020 12:00

PC Close Date & Time 03 DEC 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 12 Aug 2021 13:23:35

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**TIMEPOINT**

DAY 11

Select one response below to indicate the intensity of your **MUSCLE**

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

---

PC Time stamp

PC Open Date & Time

03 DEC 2020 12:00

PC Close Date & Time

04 DEC 2020 11:59

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US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 12 Aug 2021 13:23:35

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **MUSCLE**

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

04 DEC 2020 12:00

PC Close Date & Time

05 DEC 2020 11:59

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:23:35

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 8  |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 30 NOV 2020 16:17  |
| PC Open Date & Time   | 30 NOV 2020 12:00  |
| PC Close Date & Time  | 01 DEC 2020 11:59  |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:23:35

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 9  |
| Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 02 DEC 2020 00:31  |
| PC Open Date & Time   | 01 DEC 2020 12:00  |
| PC Close Date & Time  | 02 DEC 2020 11:59  |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 12 Aug 2021 13:23:35

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 10   |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| PC Time stamp   | 02 DEC 2020 20:13  |
| PC Open Date & Time   | 02 DEC 2020 12:00  |
| PC Close Date & Time  | 03 DEC 2020 11:59  |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 12 Aug 2021 13:23:35

|   |                              |
|---|------------------------------|
| <b>TIMEPOINT</b>  | DAY 11                       |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input type="checkbox"/>  |
|   | Yes <input type="checkbox"/> |
| PC Time stamp   |                              |
| PC Open Date & Time   | 03 DEC 2020 12:00            |
| PC Close Date & Time  | 04 DEC 2020 11:59            |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 12 Aug 2021 13:23:35

|   |                              |
|---|------------------------------|
| <b>TIMEPOINT</b>  | DAY 12                       |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input type="checkbox"/>  |
|   | Yes <input type="checkbox"/> |
| PC Time stamp   |                              |
| PC Open Date & Time   | 04 DEC 2020 12:00            |
| PC Close Date & Time  | 05 DEC 2020 11:59            |

US3712308

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3712308

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712308

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3712308

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712308

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3712308

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:45:02

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712308

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 21 DEC 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                                  |

US3712308

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

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) \_\_\_\_\_

US3712308

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

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.*

US3712308

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 DEC 2020

Collection time (00:00-23:59)

08:48 (24 HR)

Collection date and time (derived)

21 DEC 2020 08:48

US3712308

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 20:45:32

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 61

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 21:47:41

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 68   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 27 DEC 2020 23:20:56   |
| Patient Cloud Open Date & Time  | 27 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 31 DEC 2020 23:59  |

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 75   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 05 JAN 2021 12:17:20   |
| Patient Cloud Open Date & Time  | 03 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 07 JAN 2021 23:59  |

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 82   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 11 JAN 2021 09:51:57   |
| Patient Cloud Open Date & Time  | 10 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 14 JAN 2021 23:59  |

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 JAN 2021 03:48:50

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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   | 24 JAN 2021 21:05:59   |
| Patient Cloud Open Date & Time  | 24 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 28 JAN 2021 23:59  |

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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

31 JAN 2021 11:54:33

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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   | 09 FEB 2021 14:20:51   |
| Patient Cloud Open Date & Time  | 07 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 11 FEB 2021 23:59  |

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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

14 FEB 2021 11:58:26

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 124  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 21 FEB 2021 01:02:40   |
| Patient Cloud Open Date & Time  | 21 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 25 FEB 2021 23:59  |

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 131  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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 FEB 2021 19:13:42   |
| Patient Cloud Open Date & Time  | 28 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 04 MAR 2021 23:59  |

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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

07 MAR 2021 20:05:48

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 145  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 14 MAR 2021 15:51:26   |
| Patient Cloud Open Date & Time  | 14 MAR 2021 00:01  |
| Patient Cloud Close Date & Time   | 18 MAR 2021 23:59  |

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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

21 MAR 2021 14:11:22

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 03:33:41

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 166   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 173   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 00:23:44

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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06 MAY 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 201  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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09 MAY 2021 00:01

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13 MAY 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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16 MAY 2021 00:01

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20 MAY 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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27 MAY 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 222   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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03 JUN 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 229  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq$ 100.4°F/38°C)   | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 236   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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17 JUN 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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 <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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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20 JUN 2021 00:01

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24 JUN 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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01 JUL 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 264  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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°F/38°C)   | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 355   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 362   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 397   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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[Patient Cloud Close Date & Time](#)

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09 DEC 2021 23:59

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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°F/38°C)   | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐ 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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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10 FEB 2022 23:59

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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13 FEB 2022 00:01

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17 FEB 2022 23:59

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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20 FEB 2022 00:01

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24 FEB 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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10 MAR 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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17 MAR 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

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24 MAR 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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31 MAR 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐ 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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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07 APR 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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10 APR 2022 00:01

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14 APR 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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17 APR 2022 00:01

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21 APR 2022 23:59

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 649   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 656   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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> | 14 AUG 2022 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 18 AUG 2022 23:59 |
|---|-------------------|

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐ 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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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08 SEP 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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15 SEP 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 698   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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18 SEP 2022 00:01

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22 SEP 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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29 SEP 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 712   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq$ 100.4°F/38°C)   | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 719   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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°F/38°C)   | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

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US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐ 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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**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 ☐

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 DEC 2022 23:59 |

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| TIMEPOINT   | DAY 789   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 DEC 2022 23:59 |

US3712308

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:23:35

| 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"/>   |

**US3712308**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

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

[Patient Cloud Close Date & Time](#)

29 DEC 2022 23:59

US3712308

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:23:35

| 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 |
|---|--|---------------------------|
| Yes   | No   | 27 FEB 2021 20:55:30      |

US3712308

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 23:53:27

Generated On: 12 Aug 2021 13:23:35

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

SUBJECT IN ILLNESS VISIT

*If Contact Not Made, please provide Comments*

US3712308

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 02:39:58

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712308

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:00:38

Generated On: 12 Aug 2021 13:23:35

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

SUBJECT IN ILLNESS VISIT

*If Contact Not Made, please provide Comments*

US3712308

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:00:38

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712308

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:00:38

Generated On: 12 Aug 2021 13:23:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3712308

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:00:38

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3712308**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

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*

**US3712308**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|  |  |
|--|--|
| Date of Contact                                  | 06 JAN 2021  |
| Time of Contact                                  | 15:52  |
| Date and Time of Contact (derived)               | 06 JAN 2021 15:52  |
| Type of Contact                                  | <div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>  |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                  |
|--------|----------------------------------|
| Day 1  | <input checked="" type="radio"/> |
| Day 2  | <input type="radio"/>            |
| Day 3  | <input type="radio"/>            |
| Day 4  | <input type="radio"/>            |
| Day 5  | <input type="radio"/>            |
| Day 6  | <input type="radio"/>            |
| Day 7  | <input type="radio"/>            |
| Day 8  | <input type="radio"/>            |
| Day 9  | <input type="radio"/>            |
| Day 10 | <input type="radio"/>            |
| Day 11 | <input type="radio"/>            |
| Day 12 | <input type="radio"/>            |
| Day 13 | <input type="radio"/>            |
| Day 14 | <input type="radio"/>            |
| Day 15 | <input type="radio"/>            |
| Day 16 | <input type="radio"/>            |
| Day 17 | <input type="radio"/>            |
| Day 18 | <input type="radio"/>            |
| Day 19 | <input type="radio"/>            |
| Day 20 | <input type="radio"/>            |
| Day 21 | <input type="radio"/>            |
| Day 22 | <input type="radio"/>            |
| Day 23 | <input type="radio"/>            |
| Day 24 | <input type="radio"/>            |
| Day 25 | <input type="radio"/>            |
| Day 26 | <input type="radio"/>            |
| Day 27 | <input type="radio"/>            |
| Day 28 | <input type="radio"/>            |
| Day 29 | <input type="radio"/>            |
| Day 30 | <input type="radio"/>            |
| Day 31 | <input type="radio"/>            |
| Day 32 | <input type="radio"/>            |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                      |               |                                  |
|----------------------|---------------|----------------------------------|
|                      | Day 33        | <input type="checkbox"/>         |
|                      | Day 34        | <input type="checkbox"/>         |
|                      | Day 35        | <input type="checkbox"/>         |
|                      | Day 36        | <input type="checkbox"/>         |
|                      | Day 37        | <input type="checkbox"/>         |
|                      | Day 38        | <input type="checkbox"/>         |
|                      | Day 39        | <input type="checkbox"/>         |
|                      | Day 40        | <input type="checkbox"/>         |
| Date                 | 04 JAN 2021   |                                  |
| Assessment Not Done  | False         |                                  |
| O2 Saturation        | ND - Not Done |                                  |
| O2 Saturation Units  | %             |                                  |
| Temperature          | ND - Not Done |                                  |
| Chills               | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Cough                | None          | <input type="radio"/>            |
|                      | Mild          | <input checked="" type="radio"/> |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Shortness of Breath  | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Difficulty Breathing | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |

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EAB) (1725)

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input checked="" type="checkbox"/> |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                      |               |                                  |
|----------------------|---------------|----------------------------------|
|                      | Day 33        | <input type="checkbox"/>         |
|                      | Day 34        | <input type="checkbox"/>         |
|                      | Day 35        | <input type="checkbox"/>         |
|                      | Day 36        | <input type="checkbox"/>         |
|                      | Day 37        | <input type="checkbox"/>         |
|                      | Day 38        | <input type="checkbox"/>         |
|                      | Day 39        | <input type="checkbox"/>         |
|                      | Day 40        | <input type="checkbox"/>         |
| Date                 | 05 JAN 2021   |                                  |
| Assessment Not Done  | False         |                                  |
| O2 Saturation        | ND - Not Done |                                  |
| O2 Saturation Units  | %             |                                  |
| Temperature          | ND - Not Done |                                  |
| Chills               | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Cough                | None          | <input type="radio"/>            |
|                      | Mild          | <input checked="" type="radio"/> |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Shortness of Breath  | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Difficulty Breathing | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input checked="" type="radio"/> |
|                        | Mild     | <input type="radio"/>            |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input checked="" type="checkbox"/> |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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|                      |               |                                  |
|----------------------|---------------|----------------------------------|
|                      | Day 33        | <input type="checkbox"/>         |
|                      | Day 34        | <input type="checkbox"/>         |
|                      | Day 35        | <input type="checkbox"/>         |
|                      | Day 36        | <input type="checkbox"/>         |
|                      | Day 37        | <input type="checkbox"/>         |
|                      | Day 38        | <input type="checkbox"/>         |
|                      | Day 39        | <input type="checkbox"/>         |
|                      | Day 40        | <input type="checkbox"/>         |
| Date                 | 06 JAN 2021   |                                  |
| Assessment Not Done  | False         |                                  |
| O2 Saturation        | ND - Not Done |                                  |
| O2 Saturation Units  | %             |                                  |
| Temperature          | ND - Not Done |                                  |
| Chills               | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Cough                | None          | <input type="radio"/>            |
|                      | Mild          | <input checked="" type="radio"/> |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Shortness of Breath  | None          | <input type="radio"/>            |
|                      | Mild          | <input checked="" type="radio"/> |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |
|                      | Not Done      | <input type="radio"/>            |
| Difficulty Breathing | None          | <input checked="" type="radio"/> |
|                      | Mild          | <input type="radio"/>            |
|                      | Moderate      | <input type="radio"/>            |
|                      | Severe        | <input type="radio"/>            |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input checked="" type="checkbox"/> |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 07 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 37.2 C      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input checked="" type="checkbox"/> |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 08 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 99.4 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (6)

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Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input checked="" type="checkbox"/> |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 09 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 97 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.6 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input checked="" type="checkbox"/> |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 00:44:22

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|  |        |                          |
|--|--------|--------------------------|
|  | Day 33 | <input type="checkbox"/> |
|  | Day 34 | <input type="checkbox"/> |
|  | Day 35 | <input type="checkbox"/> |
|  | Day 36 | <input type="checkbox"/> |
|  | Day 37 | <input type="checkbox"/> |
|  | Day 38 | <input type="checkbox"/> |
|  | Day 39 | <input type="checkbox"/> |
|  | Day 40 | <input type="checkbox"/> |

|      |             |
|------|-------------|
| Date | 10 JAN 2021 |
|------|-------------|

|                     |       |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

|               |       |
|---------------|-------|
| O2 Saturation | 100 % |
|---------------|-------|

|                     |   |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

|             |        |
|-------------|--------|
| Temperature | 98.0 F |
|-------------|--------|

|        |                                       |
|--------|---------------------------------------|
| Chills | None <input checked="" type="radio"/> |
|        | Mild <input type="radio"/>            |
|        | Moderate <input type="radio"/>        |
|        | Severe <input type="radio"/>          |
|        | Not Done <input type="radio"/>        |

|       |                                       |
|-------|---------------------------------------|
| Cough | None <input type="radio"/>            |
|       | Mild <input checked="" type="radio"/> |
|       | Moderate <input type="radio"/>        |
|       | Severe <input type="radio"/>          |
|       | Not Done <input type="radio"/>        |

|                     |                                       |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input type="radio"/>            |
|                     | Mild <input checked="" type="radio"/> |
|                     | Moderate <input type="radio"/>        |
|                     | Severe <input type="radio"/>          |
|                     | Not Done <input type="radio"/>        |

|                      |                                       |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
|                      | Mild <input type="radio"/>            |
|                      | Moderate <input type="radio"/>        |
|                      | Severe <input type="radio"/>          |

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Generated On: 12 Aug 2021 13:23:35

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input checked="" type="checkbox"/> |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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Form: Symptom Log (8)

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|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 11 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 98 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.3 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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Form: Symptom Log (8)

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Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input checked="" type="checkbox"/> |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 00:44:22

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|  |        |                          |
|--|--------|--------------------------|
|  | Day 33 | <input type="checkbox"/> |
|  | Day 34 | <input type="checkbox"/> |
|  | Day 35 | <input type="checkbox"/> |
|  | Day 36 | <input type="checkbox"/> |
|  | Day 37 | <input type="checkbox"/> |
|  | Day 38 | <input type="checkbox"/> |
|  | Day 39 | <input type="checkbox"/> |
|  | Day 40 | <input type="checkbox"/> |

|      |             |
|------|-------------|
| Date | 12 JAN 2021 |
|------|-------------|

|                     |       |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

|               |      |
|---------------|------|
| O2 Saturation | 97 % |
|---------------|------|

|                     |   |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

|             |        |
|-------------|--------|
| Temperature | 98.1 F |
|-------------|--------|

|        |                                       |
|--------|---------------------------------------|
| Chills | None <input checked="" type="radio"/> |
|        | Mild <input type="radio"/>            |
|        | Moderate <input type="radio"/>        |
|        | Severe <input type="radio"/>          |
|        | Not Done <input type="radio"/>        |

|       |                                       |
|-------|---------------------------------------|
| Cough | None <input type="radio"/>            |
|       | Mild <input checked="" type="radio"/> |
|       | Moderate <input type="radio"/>        |
|       | Severe <input type="radio"/>          |
|       | Not Done <input type="radio"/>        |

|                     |                                       |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input type="radio"/>            |
|                     | Mild <input checked="" type="radio"/> |
|                     | Moderate <input type="radio"/>        |
|                     | Severe <input type="radio"/>          |
|                     | Not Done <input type="radio"/>        |

|                      |                                       |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input checked="" type="radio"/> |
|                      | Mild <input type="radio"/>            |
|                      | Moderate <input type="radio"/>        |
|                      | Severe <input type="radio"/>          |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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Form: Symptom Log (9)

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Generated On: 12 Aug 2021 13:23:35

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Form: Symptom Log (10)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input checked="" type="checkbox"/> |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 13 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 96 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.0 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input checked="" type="checkbox"/> |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 14 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 96 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.1 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input checked="" type="checkbox"/> |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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|                             |             |                                  |
|-----------------------------|-------------|----------------------------------|
|                             | Day 33      | <input type="checkbox"/>         |
|                             | Day 34      | <input type="checkbox"/>         |
|                             | Day 35      | <input type="checkbox"/>         |
|                             | Day 36      | <input type="checkbox"/>         |
|                             | Day 37      | <input type="checkbox"/>         |
|                             | Day 38      | <input type="checkbox"/>         |
|                             | Day 39      | <input type="checkbox"/>         |
|                             | Day 40      | <input type="checkbox"/>         |
| Date                        | 15 JAN 2021 |                                  |
| Assessment Not Done         | False       |                                  |
| O2 Saturation               | 88 %        |                                  |
| O2 Saturation Units         | %           |                                  |
| Temperature                 | 98.0 F      |                                  |
| Chills                      | None        | <input checked="" type="radio"/> |
|                             | Mild        | <input type="radio"/>            |
|                             | Moderate    | <input type="radio"/>            |
|                             | Severe      | <input type="radio"/>            |
|                             | Not Done    | <input type="radio"/>            |
| Cough                       | None        | <input type="radio"/>            |
|                             | Mild        | <input checked="" type="radio"/> |
|                             | Moderate    | <input type="radio"/>            |
|                             | Severe      | <input type="radio"/>            |
|                             | Not Done    | <input type="radio"/>            |
| Shortness of Breath         | None        | <input type="radio"/>            |
|                             | Mild        | <input type="radio"/>            |
|                             | Moderate    | <input checked="" type="radio"/> |
|                             | Severe      | <input type="radio"/>            |
|                             | Not Done    | <input type="radio"/>            |
| Difficulty Breathing        | None        | <input type="radio"/>            |
|                             | Mild        | <input type="radio"/>            |
|                             | Moderate    | <input checked="" type="radio"/> |
|                             | Severe      | <input type="radio"/>            |
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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Form: Symptom Log (13)

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Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input checked="" type="checkbox"/> |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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Form: Symptom Log (13)

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|  |             |                                  |
|--|-------------|----------------------------------|
|  | Day 33      | <input type="checkbox"/>         |
|  | Day 34      | <input type="checkbox"/>         |
|  | Day 35      | <input type="checkbox"/>         |
|  | Day 36      | <input type="checkbox"/>         |
|  | Day 37      | <input type="checkbox"/>         |
|  | Day 38      | <input type="checkbox"/>         |
|  | Day 39      | <input type="checkbox"/>         |
|  | Day 40      | <input type="checkbox"/>         |
| Date                                       | 16 JAN 2021 |                                  |
| Assessment Not Done                        | False       |                                  |
| O2 Saturation                              | 90 %        |                                  |
| O2 Saturation Units                        | %           |                                  |
| Temperature                                | 98.7 F      |                                  |
| Chills                                     | None        | <input checked="" type="radio"/> |
|  | Mild        | <input type="radio"/>            |
|  | Moderate    | <input type="radio"/>            |
|  | Severe      | <input type="radio"/>            |
|  | Not Done    | <input type="radio"/>            |
| Cough                                      | None        | <input type="radio"/>            |
|  | Mild        | <input checked="" type="radio"/> |
|  | Moderate    | <input type="radio"/>            |
|  | Severe      | <input type="radio"/>            |
|  | Not Done    | <input type="radio"/>            |
| Shortness of Breath                        | None        | <input type="radio"/>            |
|  | Mild        | <input type="radio"/>            |
|  | Moderate    | <input checked="" type="radio"/> |
|  | Severe      | <input type="radio"/>            |
|  | Not Done    | <input type="radio"/>            |
| Difficulty Breathing                       | None        | <input type="radio"/>            |
|  | Mild        | <input type="radio"/>            |
|  | Moderate    | <input checked="" type="radio"/> |
|  | Severe      | <input type="radio"/>            |
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Form: Symptom Log (13)

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input checked="" type="checkbox"/> |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 17 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 90 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.2 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input checked="" type="radio"/> |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input type="radio"/>            |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input checked="" type="radio"/> |
|                      | Severe      | <input type="radio"/>            |

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EAB) (1725)

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Generated On: 12 Aug 2021 13:23:35

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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Form: Symptom Log (14)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input checked="" type="checkbox"/> |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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Form: Symptom Log (15)

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|  |        |                          |
|--|--------|--------------------------|
|  | Day 33 | <input type="checkbox"/> |
|  | Day 34 | <input type="checkbox"/> |
|  | Day 35 | <input type="checkbox"/> |
|  | Day 36 | <input type="checkbox"/> |
|  | Day 37 | <input type="checkbox"/> |
|  | Day 38 | <input type="checkbox"/> |
|  | Day 39 | <input type="checkbox"/> |
|  | Day 40 | <input type="checkbox"/> |

|      |             |
|------|-------------|
| Date | 18 JAN 2021 |
|------|-------------|

|                     |       |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

|               |      |
|---------------|------|
| O2 Saturation | 94 % |
|---------------|------|

|                     |   |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

|             |        |
|-------------|--------|
| Temperature | 97.0 F |
|-------------|--------|

|        |                                       |
|--------|---------------------------------------|
| Chills | None <input checked="" type="radio"/> |
|        | Mild <input type="radio"/>            |
|        | Moderate <input type="radio"/>        |
|        | Severe <input type="radio"/>          |
|        | Not Done <input type="radio"/>        |

|       |                                       |
|-------|---------------------------------------|
| Cough | None <input type="radio"/>            |
|       | Mild <input checked="" type="radio"/> |
|       | Moderate <input type="radio"/>        |
|       | Severe <input type="radio"/>          |
|       | Not Done <input type="radio"/>        |

|                     |                                       |
|---------------------|---------------------------------------|
| Shortness of Breath | None <input type="radio"/>            |
|                     | Mild <input checked="" type="radio"/> |
|                     | Moderate <input type="radio"/>        |
|                     | Severe <input type="radio"/>          |
|                     | Not Done <input type="radio"/>        |

|                      |                                       |
|----------------------|---------------------------------------|
| Difficulty Breathing | None <input type="radio"/>            |
|                      | Mild <input checked="" type="radio"/> |
|                      | Moderate <input type="radio"/>        |
|                      | Severe <input type="radio"/>          |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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Form: Symptom Log (15)

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Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input checked="" type="checkbox"/> |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 00:44:22

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|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 19 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 94 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.4 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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EAB) (1725)

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Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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Form: Symptom Log (16)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Form: Symptom Log (17)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input checked="" type="checkbox"/> |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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Form: Symptom Log (17)

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|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 20 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 92 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.0 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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Generated On: 12 Aug 2021 13:23:35

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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Form: Symptom Log (17)

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|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Form: Symptom Log (18)

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Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input checked="" type="checkbox"/> |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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Form: Symptom Log (18)

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|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 21 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 93 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.2 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Form: Symptom Log (19)

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Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input checked="" type="checkbox"/> |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 22 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 92 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 97.4 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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Form: Symptom Log (19)

Data signed: (b) (4) 05 Apr 2021 00:44:22

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Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (20)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input checked="" type="checkbox"/> |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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|  |        |                          |
|--|--------|--------------------------|
|  | Day 33 | <input type="checkbox"/> |
|  | Day 34 | <input type="checkbox"/> |
|  | Day 35 | <input type="checkbox"/> |
|  | Day 36 | <input type="checkbox"/> |
|  | Day 37 | <input type="checkbox"/> |
|  | Day 38 | <input type="checkbox"/> |
|  | Day 39 | <input type="checkbox"/> |
|  | Day 40 | <input type="checkbox"/> |

|      |             |
|------|-------------|
| Date | 23 JAN 2021 |
|------|-------------|

|                     |       |
|---------------------|-------|
| Assessment Not Done | False |
|---------------------|-------|

|               |      |
|---------------|------|
| O2 Saturation | 92 % |
|---------------|------|

|                     |   |
|---------------------|---|
| O2 Saturation Units | % |
|---------------------|---|

|             |        |
|-------------|--------|
| Temperature | 98.1 F |
|-------------|--------|

|        |          |                                  |
|--------|----------|----------------------------------|
| Chills | None     | <input checked="" type="radio"/> |
|        | Mild     | <input type="radio"/>            |
|        | Moderate | <input type="radio"/>            |
|        | Severe   | <input type="radio"/>            |
|        | Not Done | <input type="radio"/>            |

|       |          |                                  |
|-------|----------|----------------------------------|
| Cough | None     | <input type="radio"/>            |
|       | Mild     | <input checked="" type="radio"/> |
|       | Moderate | <input type="radio"/>            |
|       | Severe   | <input type="radio"/>            |
|       | Not Done | <input type="radio"/>            |

|                     |          |                                  |
|---------------------|----------|----------------------------------|
| Shortness of Breath | None     | <input type="radio"/>            |
|                     | Mild     | <input checked="" type="radio"/> |
|                     | Moderate | <input type="radio"/>            |
|                     | Severe   | <input type="radio"/>            |
|                     | Not Done | <input type="radio"/>            |

|                      |          |                                  |
|----------------------|----------|----------------------------------|
| Difficulty Breathing | None     | <input type="radio"/>            |
|                      | Mild     | <input checked="" type="radio"/> |
|                      | Moderate | <input type="radio"/>            |
|                      | Severe   | <input type="radio"/>            |

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|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Nasal Congestion

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☐  
Mild ☒  
Moderate ☐  
Severe ☐  
Not Done ☐

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input checked="" type="checkbox"/> |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                             |             |                                  |
|-----------------------------|-------------|----------------------------------|
|                             | Day 33      | <input type="checkbox"/>         |
|                             | Day 34      | <input type="checkbox"/>         |
|                             | Day 35      | <input type="checkbox"/>         |
|                             | Day 36      | <input type="checkbox"/>         |
|                             | Day 37      | <input type="checkbox"/>         |
|                             | Day 38      | <input type="checkbox"/>         |
|                             | Day 39      | <input type="checkbox"/>         |
|                             | Day 40      | <input type="checkbox"/>         |
| Date                        | 24 JAN 2021 |                                  |
| Assessment Not Done         | False       |                                  |
| O2 Saturation               | 94 %        |                                  |
| O2 Saturation Units         | %           |                                  |
| Temperature                 | 97.0 F      |                                  |
| Chills                      | None        | <input checked="" type="radio"/> |
|                             | Mild        | <input type="radio"/>            |
|                             | Moderate    | <input type="radio"/>            |
|                             | Severe      | <input type="radio"/>            |
|                             | Not Done    | <input type="radio"/>            |
| Cough                       | None        | <input type="radio"/>            |
|                             | Mild        | <input checked="" type="radio"/> |
|                             | Moderate    | <input type="radio"/>            |
|                             | Severe      | <input type="radio"/>            |
|                             | Not Done    | <input type="radio"/>            |
| Shortness of Breath         | None        | <input type="radio"/>            |
|                             | Mild        | <input checked="" type="radio"/> |
|                             | Moderate    | <input type="radio"/>            |
|                             | Severe      | <input type="radio"/>            |
|                             | Not Done    | <input type="radio"/>            |
| Difficulty Breathing        | None        | <input type="radio"/>            |
|                             | Mild        | <input checked="" type="radio"/> |
|                             | Moderate    | <input type="radio"/>            |
|                             | Severe      | <input type="radio"/>            |
| PRODUCTION RELEASE (v12.003 |             | 448 of 3258                      |
| EAB) (1725)                 |             |                                  |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input checked="" type="checkbox"/> |
| Day 23 | <input type="checkbox"/>            |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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Form: Symptom Log (22)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|  |        |                          |
|--|--------|--------------------------|
|  | Day 33 | <input type="checkbox"/> |
|  | Day 34 | <input type="checkbox"/> |
|  | Day 35 | <input type="checkbox"/> |
|  | Day 36 | <input type="checkbox"/> |
|  | Day 37 | <input type="checkbox"/> |
|  | Day 38 | <input type="checkbox"/> |
|  | Day 39 | <input type="checkbox"/> |
|  | Day 40 | <input type="checkbox"/> |

|      |             |
|------|-------------|
| Date | 25 JAN 2021 |
|------|-------------|

|                     |      |
|---------------------|------|
| Assessment Not Done | True |
|---------------------|------|

|               |  |
|---------------|--|
| O2 Saturation |  |
|---------------|--|

|                     |  |
|---------------------|--|
| O2 Saturation Units |  |
|---------------------|--|

|             |  |
|-------------|--|
| Temperature |  |
|-------------|--|

|        |          |                          |
|--------|----------|--------------------------|
| Chills | None     | <input type="checkbox"/> |
|        | Mild     | <input type="checkbox"/> |
|        | Moderate | <input type="checkbox"/> |
|        | Severe   | <input type="checkbox"/> |
|        | Not Done | <input type="checkbox"/> |

|       |          |                          |
|-------|----------|--------------------------|
| Cough | None     | <input type="checkbox"/> |
|       | Mild     | <input type="checkbox"/> |
|       | Moderate | <input type="checkbox"/> |
|       | Severe   | <input type="checkbox"/> |
|       | Not Done | <input type="checkbox"/> |

|                     |          |                          |
|---------------------|----------|--------------------------|
| Shortness of Breath | None     | <input type="checkbox"/> |
|                     | Mild     | <input type="checkbox"/> |
|                     | Moderate | <input type="checkbox"/> |
|                     | Severe   | <input type="checkbox"/> |
|                     | Not Done | <input type="checkbox"/> |

|                      |          |                          |
|----------------------|----------|--------------------------|
| Difficulty Breathing | None     | <input type="checkbox"/> |
|                      | Mild     | <input type="checkbox"/> |
|                      | Moderate | <input type="checkbox"/> |
|                      | Severe   | <input type="checkbox"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                        |          |                          |
|------------------------|----------|--------------------------|
|                        | Not Done | <input type="checkbox"/> |
| Fatigue                | None     | <input type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/> |
|                        | Severe   | <input type="checkbox"/> |
|                        | Not Done | <input type="checkbox"/> |
| Muscle Aches (Myalgia) | None     | <input type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/> |
|                        | Severe   | <input type="checkbox"/> |
|                        | Not Done | <input type="checkbox"/> |
| Body Aches             | None     | <input type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/> |
|                        | Severe   | <input type="checkbox"/> |
|                        | Not Done | <input type="checkbox"/> |
| Headache               | None     | <input type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/> |
|                        | Severe   | <input type="checkbox"/> |
|                        | Not Done | <input type="checkbox"/> |
| New Loss of Taste      | None     | <input type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/> |
|                        | Severe   | <input type="checkbox"/> |
|                        | Not Done | <input type="checkbox"/> |
| New Loss of Smell      | None     | <input type="checkbox"/> |
|                        | Mild     | <input type="checkbox"/> |
|                        | Moderate | <input type="checkbox"/> |
|                        | Severe   | <input type="checkbox"/> |
|                        | Not Done | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                         |          |                          |
|-------------------------|----------|--------------------------|
| Nasal Congestion        | None     | <input type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/> |
|                         | Severe   | <input type="checkbox"/> |
|                         | Not Done | <input type="checkbox"/> |
| Runny Nose (Rhinorrhea) | None     | <input type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/> |
|                         | Severe   | <input type="checkbox"/> |
|                         | Not Done | <input type="checkbox"/> |
| Nausea                  | None     | <input type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/> |
|                         | Severe   | <input type="checkbox"/> |
|                         | Not Done | <input type="checkbox"/> |
| Vomiting                | None     | <input type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/> |
|                         | Severe   | <input type="checkbox"/> |
|                         | Not Done | <input type="checkbox"/> |
| Diarrhea                | None     | <input type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/> |
|                         | Severe   | <input type="checkbox"/> |
|                         | Not Done | <input type="checkbox"/> |
| Sore Throat             | None     | <input type="checkbox"/> |
|                         | Mild     | <input type="checkbox"/> |
|                         | Moderate | <input type="checkbox"/> |
|                         | Severe   | <input type="checkbox"/> |
|                         | Not Done | <input type="checkbox"/> |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Symptom Day

|        |                                     |
|--------|-------------------------------------|
| Day 1  | <input type="checkbox"/>            |
| Day 2  | <input type="checkbox"/>            |
| Day 3  | <input type="checkbox"/>            |
| Day 4  | <input type="checkbox"/>            |
| Day 5  | <input type="checkbox"/>            |
| Day 6  | <input type="checkbox"/>            |
| Day 7  | <input type="checkbox"/>            |
| Day 8  | <input type="checkbox"/>            |
| Day 9  | <input type="checkbox"/>            |
| Day 10 | <input type="checkbox"/>            |
| Day 11 | <input type="checkbox"/>            |
| Day 12 | <input type="checkbox"/>            |
| Day 13 | <input type="checkbox"/>            |
| Day 14 | <input type="checkbox"/>            |
| Day 15 | <input type="checkbox"/>            |
| Day 16 | <input type="checkbox"/>            |
| Day 17 | <input type="checkbox"/>            |
| Day 18 | <input type="checkbox"/>            |
| Day 19 | <input type="checkbox"/>            |
| Day 20 | <input type="checkbox"/>            |
| Day 21 | <input type="checkbox"/>            |
| Day 22 | <input type="checkbox"/>            |
| Day 23 | <input checked="" type="checkbox"/> |
| Day 24 | <input type="checkbox"/>            |
| Day 25 | <input type="checkbox"/>            |
| Day 26 | <input type="checkbox"/>            |
| Day 27 | <input type="checkbox"/>            |
| Day 28 | <input type="checkbox"/>            |
| Day 29 | <input type="checkbox"/>            |
| Day 30 | <input type="checkbox"/>            |
| Day 31 | <input type="checkbox"/>            |
| Day 32 | <input type="checkbox"/>            |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                      |             |                                  |
|----------------------|-------------|----------------------------------|
|                      | Day 33      | <input type="checkbox"/>         |
|                      | Day 34      | <input type="checkbox"/>         |
|                      | Day 35      | <input type="checkbox"/>         |
|                      | Day 36      | <input type="checkbox"/>         |
|                      | Day 37      | <input type="checkbox"/>         |
|                      | Day 38      | <input type="checkbox"/>         |
|                      | Day 39      | <input type="checkbox"/>         |
|                      | Day 40      | <input type="checkbox"/>         |
| Date                 | 26 JAN 2021 |                                  |
| Assessment Not Done  | False       |                                  |
| O2 Saturation        | 96 %        |                                  |
| O2 Saturation Units  | %           |                                  |
| Temperature          | 98.2 F      |                                  |
| Chills               | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Cough                | None        | <input checked="" type="radio"/> |
|                      | Mild        | <input type="radio"/>            |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Shortness of Breath  | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |
|                      | Not Done    | <input type="radio"/>            |
| Difficulty Breathing | None        | <input type="radio"/>            |
|                      | Mild        | <input checked="" type="radio"/> |
|                      | Moderate    | <input type="radio"/>            |
|                      | Severe      | <input type="radio"/>            |

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                        |          |                                  |
|------------------------|----------|----------------------------------|
|                        | Not Done | <input type="radio"/>            |
| Fatigue                | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Muscle Aches (Myalgia) | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Body Aches             | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| Headache               | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Taste      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |
| New Loss of Smell      | None     | <input type="radio"/>            |
|                        | Mild     | <input checked="" type="radio"/> |
|                        | Moderate | <input type="radio"/>            |
|                        | Severe   | <input type="radio"/>            |
|                        | Not Done | <input type="radio"/>            |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                         |          |                                  |
|-------------------------|----------|----------------------------------|
| Nasal Congestion        | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Runny Nose (Rhinorrhea) | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Nausea                  | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Vomiting                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Diarrhea                | None     | <input checked="" type="radio"/> |
|                         | Mild     | <input type="radio"/>            |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |
| Sore Throat             | None     | <input type="radio"/>            |
|                         | Mild     | <input checked="" type="radio"/> |
|                         | Moderate | <input type="radio"/>            |
|                         | Severe   | <input type="radio"/>            |
|                         | Not Done | <input type="radio"/>            |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Date of Visit 07 JAN 2021

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒  
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☒  
No ☐

Date of Test 07 JAN 2021

Type of Test Performed Nasopharyngeal Swab ☒  
Nasal Swab ☐  
Saliva Test ☐  
Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐  
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐  
No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 15 JAN 2021

End Date 17 JAN 2021

Oxygen Saturation 88 %

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Hepatic Dysfunction? Yes ☐  
No ☒

Start Date

Neurologic Dysfunction? Yes ☐  
No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐  
No ☒

Date of Assessment

Radiographical Evidence Yes ☐  
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐  
No ☒

Start Date

End Date

US3712308

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 00:44:23

Generated On: 12 Aug 2021 13:23:35

| Visit  | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3  | Yes                   | 08 JAN 2021        |
| Day 5  | Yes                   | 11 JAN 2021        |
| Day 7  | No                    |                    |
| Day 9  | No                    |                    |
| Day 14 | No                    |                    |
| Day 21 | Yes                   | 26 JAN 2021        |
| Day 28 | Yes                   | 04 FEB 2021        |

US3712308

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:44:23

Generated On: 12 Aug 2021 13:23:35

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 07 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  | SICKD1                                  |

US3712308

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 00:44:23

Generated On: 12 Aug 2021 13:23:35

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 07 JAN 2021                           |
| Time of assessment (00:00-23:59)    | 13:07 (24 HR)                         |
| Vital Signs Date and Time (derived) | 07 JAN 2021 13:07                     |
| Height (xxx.x)                      | 161.5 cm                              |
| Weight (xxx.x)                      | 89.1 kg                               |
| Temperature (xxx.x)                 | 37.2 C                                |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 89 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 16 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 141 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 99 mmHg                               |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |

US3712308

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:44:23

Generated On: 12 Aug 2021 13:23:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 JAN 2021

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

US3712308

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Apr 2021 00:44:23

Generated On: 12 Aug 2021 13:23:35

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

07 JAN 2021

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 04 FEB 2021                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | SICKD28                                 |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 04 FEB 2021                           |
| Time of assessment (00:00-23:59)    | 07:20 (24 HR)                         |
| Vital Signs Date and Time (derived) | 04 FEB 2021 07:20                     |
| Height (xxx.x)                      | 161.5 cm                              |
| Weight (xxx.x)                      | 89.1 kg                               |
| 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)                         | 85 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 16 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 130 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 88 mmHg                               |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 FEB 2021

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

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

04 FEB 2021

US3712308

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 00:44:23

Generated On: 12 Aug 2021 13:23:35

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 19 FEB 2021 |
|--------------------------|-------------|

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

|            |               |
|------------|---------------|
| Folder OID | UNBLND_DECIDE |
|------------|---------------|

US3712308

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 00:44:23

Generated On: 12 Aug 2021 13:23:35

|   |   |
|---|---|
| Date of updated informed consent ( <i>dd MMM yyyy</i> )               | 19 FEB 2021   |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | False   |
| Was the participant unblinded?  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>  |
| Under what version of the Protocol was the Participant unblinded?     | Amendment 5 <input type="radio"/><br>Amendment 6 or later <input checked="" type="radio"/>                            |
| Date of unblinding ( <i>dd MMM yyyy</i> )                             | 19 FEB 2021   |
| Participant randomization assignment                                  | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/>   |
| Actual Dose 1   | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/><br>Not Administered <input type="radio"/> |
| Actual Dose 2   | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/><br>Not Administered <input type="radio"/> |
| Will participant receive mRNA-1273?                                   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>  |
| Placebo Only Flag   | 1   |
| Continuing with mRNA-1273   | 1   |

US3712308

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Apr 2021 01:00:38

Generated On: 12 Aug 2021 13:23:35

|             |               |
|-------------|---------------|
| Height      | ND - Not Done |
| Weight      | ND - Not Done |
| BMI (xxx.x) |               |

US3712308

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Apr 2021 01:00:38

Generated On: 12 Aug 2021 13:23:35

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| BMI (xxx.x)                         |  |
| Timepoint                           | Pre-Dose <input checked="" type="radio"/><br>Post-Dose <input type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 19 FEB 2021  |
| Time of assessment (00:00-23:59)    | 09:20 (24 HR)  |
| Vital Signs Date and Time (derived) | 19 FEB 2021 09:20  |
| Temperature (xxx.x)                 | 36.9 C   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 90 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 126 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 81 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3712308

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Apr 2021 01:00:38

Generated On: 12 Aug 2021 13:23:35

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| BMI (xxx.x)                         |  |
| Timepoint                           | Pre-Dose <input type="radio"/><br>Post-Dose <input checked="" type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 19 FEB 2021  |
| Time of assessment (00:00-23:59)    | 11:02 (24 HR)  |
| Vital Signs Date and Time (derived) | 19 FEB 2021 11:02  |
| Temperature (xxx.x)                 | 37.0 C   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 84 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 127 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 82 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3712308

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

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 00:44:23

Generated On: 12 Aug 2021 13:23:35

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.*

US3712308

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

Form: Pregnancy Test

Data signed: (b) (4) 05 Apr 2021 00:44:23

Generated On: 12 Aug 2021 13:23:35

|                                     |   |
|-------------------------------------|---|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 19 FEB 2021                               |
| Test performed                      | Urine <input checked="" type="radio"/>    |
|                                     | Serum <input type="radio"/>               |
| Result                              | Positive <input type="radio"/>            |
|                                     | Negative <input checked="" type="radio"/> |
| Was FSH sample collected?           | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Collection date                     |   |
| Collection time                     |   |
| Collection date and time (derived)  |   |

US3712308

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

Form: Exposure

Data signed: (b) (4) 05 Apr 2021 00:44:23

Generated On: 12 Aug 2021 13:23:35

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 FEB 2021

What was the treatment time? (00:00-23:59) 10:32 (24 HR)

Treatment Date and Time (derived) 19 FEB 2021 10:32

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

What was the frequency of the study treatment dosing? ONCE

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

US3712308

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 00:44:23

Generated On: 12 Aug 2021 13:23:35

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

|                               |             |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 19 FEB 2021 |
|-------------------------------|-------------|

|                               |               |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 09:25 (24 HR) |
|-------------------------------|---------------|

|                                    |                   |
|------------------------------------|-------------------|
| Collection date and time (derived) | 19 FEB 2021 09:25 |
|------------------------------------|-------------------|

US3712308

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 00:44:23

Generated On: 12 Aug 2021 13:23:35

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 19 FEB 2021                          |
| Collection time (00:00 - 23:59)    | 09:25                                |
| Collection Date and Time (derived) | 19 FEB 2021 09:25                    |

US3712308

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

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 00:44:23

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712308

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 01:00:38

Generated On: 12 Aug 2021 13:23:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3712308

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 01:00:38

Generated On: 12 Aug 2021 13:23:35

|  |                                      |
|--|--------------------------------------|
| Is the participant continuing to the next visit? | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Continuing Flag                                  | 1                                    |
| OLD29 Placebo Flag                               | 1                                    |

US3712308

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 01:14:51

Generated On: 12 Aug 2021 13:23:35

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 26 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  | OLD29                                   |

US3712308

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Apr 2021 01:14:51

Generated On: 12 Aug 2021 13:23:35

|                                     |   |
|-------------------------------------|---|
| 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)    | 26 MAR 2021                               |
| Time of assessment (00:00-23:59)    | 14:01 (24 HR)                             |
| Vital Signs Date and Time (derived) | 26 MAR 2021 14:01                         |
| Temperature (xxx.x)                 | 37.2 C                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 76 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 16 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 122 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 81 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3712308

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Apr 2021 01:14:51

Generated On: 12 Aug 2021 13:23:35

|                                     |  |
|-------------------------------------|--|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>       |
|                                     | No <input type="radio"/>                   |
| Date of assessment (dd MMM yyyy)    | 26 MAR 2021                                |
| Time of assessment (00:00-23:59)    | 15:14 (24 HR)                              |
| Vital Signs Date and Time (derived) | 26 MAR 2021 15:14                          |
| Temperature (xxx.x)                 | 37.0 C                                     |
| Route of measurement                | Oral <input checked="" type="radio"/>      |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |  |
| Pulse (xxx)                         | 73 beats/min                               |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 127 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 82 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3712308

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 01:14:51

Generated On: 12 Aug 2021 13:23:35

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.*

US3712308

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 12 Apr 2021 01:14:51

Generated On: 12 Aug 2021 13:23:35

|                                     |   |
|-------------------------------------|---|
| Was the pregnancy test performed?   | Yes <input checked="" type="radio"/>      |
|                                     | No <input type="radio"/>                  |
| Date of test ( <i>dd MMM yyyy</i> ) | 26 MAR 2021                               |
| Test performed                      | Urine <input checked="" type="radio"/>    |
|                                     | Serum <input type="radio"/>               |
| Result                              | Positive <input type="radio"/>            |
|                                     | Negative <input checked="" type="radio"/> |
| Was FSH sample collected?           | Yes <input type="radio"/>                 |
|                                     | No <input checked="" type="radio"/>       |
| Collection date                     |   |
| Collection time                     |   |
| Collection date and time (derived)  |   |

US3712308

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Apr 2021 01:14:51

Generated On: 12 Aug 2021 13:23:35

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 26 MAR 2021

What was the treatment time? (00:00-23:59) 14:44 (24 HR)

Treatment Date and Time (derived) 26 MAR 2021 14:44

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

US3712308

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 01:14:51

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3712308

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 01:14:51

Generated On: 12 Aug 2021 13:23:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3712308

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 01:14:51

Generated On: 12 Aug 2021 13:23:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3712308**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_

US3712308

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

|   |                                   |
|---|-----------------------------------|
| Were vital signs assessed?                | Yes <input type="checkbox"/>      |
|   | No <input type="checkbox"/>       |
| Date of assessment ( <i>dd MMM yyyy</i> ) |                                   |
| Time of assessment ( <i>00:00-23:59</i> ) |                                   |
| Vital Signs Date and Time (derived)       |                                   |
| Temperature ( <i>xxx.x</i> )              |                                   |
| Route of measurement                      | Oral <input type="checkbox"/>     |
|   | Axillary <input type="checkbox"/> |
|   | Other <input type="checkbox"/>    |
| If Other, specify                         |                                   |
| Pulse ( <i>xxx</i> )                      |                                   |
| Pulse units                               |                                   |
| Respiratory Rate ( <i>xxx</i> )           |                                   |
| Respiratory Rate units                    |                                   |
| Systolic Blood Pressure ( <i>xxx</i> )    |                                   |
| Systolic Blood Pressure units             |                                   |
| Diastolic Blood Pressure ( <i>xxx</i> )   |                                   |
| Diastolic Blood Pressure units            |                                   |
| Height (derived)                          |                                   |
| Weight (derived)                          |                                   |

US3712308

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:35

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.*

**US3712308**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:23:35**

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

|  |       |
|--|-------|
| Collection date ( <i>dd MMM yyyy</i> ) | _____ |
| Collection time ( <i>00:00-23:59</i> ) | _____ |
| Collection date and time (derived)     | _____ |

US3712308

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 22:30:13

Generated On: 12 Aug 2021 13:23:35

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3712308

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | COVID 19   |
| 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 checked="" type="radio"/><br>No <input type="radio"/>   |
| Start date (dd MMM yyyy)                                       | 04 JAN 2021  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         |  |
| 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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US3712308

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

|  |   |
|--|---|
| 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 <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>   |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input checked="" 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)                         |   |

US3712308

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | FATIGUE  |
| Was this a medically-attended AE?                              | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| Was this a Solicited Adverse Reaction?                         | Yes <input checked="" type="radio"/><br>No <input 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)                                       | 27 OCT 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)                         | 30 OCT 2020  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input checked="" type="radio"/><br>Grade 2/Moderate <input 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 (2)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

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

US3712308

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

AEID

Adverse event

HEADACHE

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)

23 OCT 2020

Start time (00:00-23:59)

18:00 (24 HR)

AE start date and time (derived)

23 OCT 2020 18:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 NOV 2020

End time (00:00-23:59)

08:00 (24 HR)

AE End Date and Time (derived)

03 NOV 2020 08:00

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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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

AEID

Adverse event

MUSCLE ACHES

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)

29 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 NOV 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)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

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

US3712308

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | MUSCLE ACHES   |
| Was this a medically-attended AE?                              | Yes <input type="radio"/><br>No <input checked="" 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)                                       | 28 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)                         | 02 DEC 2020  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input checked="" type="radio"/><br>Grade 2/Moderate <input 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 (5)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

|  |  |
|--|--|
| AEID   |  |
| Adverse event  | SI JOINT INFLAMMATION  |
| 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)                                       | 23 MAR 2021  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         |  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input checked="" type="radio"/><br>Grade 2/Moderate <input 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 (6)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

|   |   |
|---|---|
| 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 <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>   |
| Other action taken (check all that apply)   |   |
| None  | False   |
| Concomitant Medication  | True  |
| Concomitant Procedure   | False   |
| Outcome   | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input checked="" type="radio"/><br>Recovered/Resolved <input type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:<br>_____ |   |
| Narrative<br>_____  |   |
| Serious Adverse Event Derived (CSA Programming Field Only)                            | 0   |
| Medically Attended AE Derived (CSA Programming Field Only)                            | 1   |
| Admitted to ICU Derived (CSA Programming Field Only)<br>_____                         |   |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

---

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

Yes ☒

No ☐

---

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

---

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

Name of Medication NUVA RING

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

Dose per administration 120/15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input checked="" type="checkbox"/> |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | UN                       | UNK 2000                            |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input type="checkbox"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | 1                        |                                     |
| Interval Dosage Unit Number (derived)              | 1                        |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input checked="" type="checkbox"/> |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 18 Apr 2021 23:32:09

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 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"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 18 Apr 2021 23:32:09

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Name of Medication CELEXA

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2012              |                                  |
| 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 (4)

Data signed: (b) (4) 18 Apr 2021 23:32:09

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Name of Medication WELLBUTRIN

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 18 Apr 2021 23:32:09

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2012              |                                  |
| 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) 18 Apr 2021 23:32:09

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Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 18 Apr 2021 23:32:09

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2008              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 23:32:09

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Name of Medication SINGULAIR

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 18 Apr 2021 23:32:09

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2016              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Apr 2021 23:32:09

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Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 18 Apr 2021 23:32:09

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2008              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 18 Apr 2021 23:32:09

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Name of Medication PHENTERMINE

Prophylaxis Yes ☐  
No ☒

Indication WEIGHT LOSS

Dose per administration 37.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2019              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | _____                    |                                  |
| Interval Dosage Unit Number (derived)              | _____                    |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Apr 2021 23:32:09

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Name of Medication VALSARTAN HCTZ

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 160/12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 18 Apr 2021 23:32:09

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2017              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 18 Apr 2021 23:32:09

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Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication COVID 19

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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Form: Prior/Concomitant Medication and Vaccination (10)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | 04 JAN 2021              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | _____                    |                                  |
| Interval Dosage Unit Number (derived)              | _____                    |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

|  |                              |                                     |
|--|------------------------------|-------------------------------------|
|  | 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 2008                            |
| Start date completely unknown                      | False                        |                                     |
| Ongoing?   | Yes <input type="checkbox"/> | No <input checked="" type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 13                           | NOV 2020                            |
| Was this medication taken for solicited event?     | Yes <input type="checkbox"/> | No <input checked="" type="radio"/> |
| 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="radio"/>    |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

Name of Medication NEXIUM

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           |                          | 15 NOV 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"/> |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

Name of Medication BOTOX

Prophylaxis Yes ☐  
No ☒

Indication ELECTIVE COSMETIC

Dose per administration 20

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

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

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

Name of Medication MOBIC

Prophylaxis Yes ☐  
No ☒

Indication SI JOINT INFLAMMATION

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 18 Apr 2021 23:32:09

Generated On: 12 Aug 2021 13:23:35

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           | 23 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 type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

US3712308

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 00:44:22

Generated On: 12 Aug 2021 13:23:35

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3712308

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:23:35

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 ☐

Audit

US3712308 (Prod: Alliance for Multispecialty Research, LLC)

**US3712308**

**Form: Participant Creation**

**Generated On: 12 Aug 2021 13:23:35**

[Participant ID](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| User signature succeeded. | William Smith (b) (4)                       | 05 Apr 2021 00:44:24 |
| User entered 'US3712308'  | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 23 Oct 2020 17:28:39 |

US3712308

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:23:35

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Oct 2020 21:33:57 |

US3712308

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:23:35

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)                       | 13 Feb 2021 20:45:32 |
| User entered '23 OCT 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 23 Oct 2020 17:28:40 |

US3712308

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:23:35

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.      | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 23 Oct 2020 21:33:57 |

**US3712308**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'SCRN' | System           | 23 Oct 2020 21:33:57 |

US3712308

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:35

[Date of Birth \(MMM yyyy\)](#)

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)            | 13 Feb 2021 20:45:03 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 10 Feb 2021 20:23:33 |
| User entered (b) (6) 1973' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 23 Oct 2020 17:28:41 |

**US3712308**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:23:35**

[Age](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:23:33 |
| User entered '46'         | (b) (4), (b) (6)            | 26 Oct 2020 14:51:06 |

**US3712308**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:23:35**

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'YEARS' | System           | 26 Oct 2020 14:51:06 |

**US3712308**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:23:35**

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '47' | System           | 23 Oct 2020 21:34:14 |

**US3712308**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:23:35**

[Sex](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:23:33 |
| User entered 'Female (F)' | (b) (4), (b) (6)            | 26 Oct 2020 14:51:06 |

US3712308

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:23:35

[Ethnicity](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.                                      | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:23:33 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4), (b) (6)            | 26 Oct 2020 14:51:06 |

**US3712308**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:23:35**

[White](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 20:23:33 |
| User entered 'l'          | (b) (4), (b) (6)      | 26 Oct 2020 14:51:06 |

**US3712308**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:23:35**

[Black](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:23:33 |
| User entered '0'          | (b) (4), (b) (6)            | 26 Oct 2020 14:51:06 |

**US3712308**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:23:35**

[Asian](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:23:33 |
| User entered '0'          | (b) (4), (b) (6)            | 26 Oct 2020 14:51:06 |

**US3712308**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:23:35**

[American Indian or Alaska Native](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 20:23:33 |
| User entered '0'          | (b) (4), (b) (6)      | 26 Oct 2020 14:51:06 |

**US3712308**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:23:35**

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 20:23:33 |
| User entered '0'          | (b) (4), (b) (6)      | 26 Oct 2020 14:51:06 |

**US3712308**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:23:35**

[Other](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:23:33 |
| User entered '0'          | (b) (4), (b) (6)            | 26 Oct 2020 14:51:06 |

**US3712308**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:23:35**

[If race is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 20:23:33 |
| User entered empty.       | (b) (4), (b) (6)      | 26 Oct 2020 14:51:06 |

**US3712308**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:23:35**

[Unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 20:23:33 |
| User entered '0'          | (b) (4), (b) (6)      | 26 Oct 2020 14:51:06 |

**US3712308**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:23:35**

[Not reported](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:23:33 |
| User entered '0'          | (b) (4), (b) (6)            | 26 Oct 2020 14:51:06 |

US3712308

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:23:35

Date of Informed Consent (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:24:27 |
| User entered '23 Oct 2020' | (b) (4), (b) (6)            | 23 Oct 2020 21:34:14 |

**US3712308**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Oct 2020' | System           | 23 Oct 2020 21:34:14 |

**US3712308**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2020' | System           | 23 Oct 2020 21:34:14 |

**US3712308**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:23:35**

[Protocol Version](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.      | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:24:27 |
| User entered 'Amendment 4 (4)' | (b) (4), (b) (6)            | 23 Oct 2020 21:34:14 |

**US3712308**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:24:27 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 23 Oct 2020 21:34:14 |

**US3712308**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:23:35**

[If No, indicate reason for screen fail](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:24:27 |
| User entered empty.       | (b) (4), (b) (6)            | 23 Oct 2020 21:34:14 |

**US3712308**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:23:35**

If reason for screen fail is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:24:27 |
| User entered empty.       | (b) (4), (b) (6)            | 23 Oct 2020 21:34:14 |

**US3712308**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:23:35**

[Was this participant screened previously?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:24:27 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 23 Oct 2020 21:34:14 |

**US3712308**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:23:35**

[If Yes, previous participant number](#)

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)            | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 10 Feb 2021 20:24:27 |
| User entered empty.       | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 23 Oct 2020 17:28:40 |

**US3712308**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:23:35**

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '1'  | System           | 23 Oct 2020 21:34:18 |

US3712308

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:27:17 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 23 Oct 2020 21:34:18 |

**US3712308**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 12 Aug 2021 13:23:35**

[Were any significant conditions reported?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:07:41 |

US3712308

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:23:35

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| 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: Allergy to antibiotic - version MedDRA\\23.0. | Coder Import (b) (4)  | 26 Oct 2020 15:20:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 26 Oct 2020 15:20:40 |
| Data point term sent to Coder   | System                | 26 Oct 2020 15:08:27 |
| User entered 'allergy to levaquin'  | (b) (4), (b) (6)      | 26 Oct 2020 15:08:10 |

**US3712308**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2006' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:10 |

**US3712308**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:10 |

**US3712308**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:10 |

**US3712308**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:10 |

**US3712308**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:10 |

**US3712308**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2006' | System           | 26 Oct 2020 15:08:10 |

**US3712308**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2006' | System           | 26 Oct 2020 15:08:10 |

**US3712308**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:08:10 |

**US3712308**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:08:10 |

US3712308

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:23:35

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental disorders NEC, PT: Tooth impacted, LLT: Impacted wisdom tooth - version MedDRA\\23.0. | Coder Import (b) (4)  | 26 Oct 2020 15:20:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 26 Oct 2020 15:20:39 |
| Data point term sent to Coder   | System                | 26 Oct 2020 15:08:27 |
| User entered 'wisdom teeth impaction'   | (b) (4), (b) (6)      | 26 Oct 2020 15:08:24 |

**US3712308**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 1993' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:24 |

**US3712308**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:24 |

**US3712308**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:24 |

**US3712308**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 1993' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:24 |

**US3712308**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:24 |

**US3712308**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 1993' | System           | 26 Oct 2020 15:08:24 |

**US3712308**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '1993' | System           | 26 Oct 2020 15:08:24 |

**US3712308**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 1993' | System           | 26 Oct 2020 15:08:24 |

**US3712308**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '1993' | System           | 26 Oct 2020 15:08:24 |

US3712308

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:35

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Wisdom teeth removal, LLT: Wisdom teeth removal - version MedDRA\\23.0. | Coder Import (b) (4)  | 26 Oct 2020 15:22:15 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 26 Oct 2020 15:22:15 |
| Data point term sent to Coder   | System                | 26 Oct 2020 15:09:28 |
| User entered 'wisdom teeth extraction'  | (b) (4), (b) (6)      | 26 Oct 2020 15:08:39 |

US3712308

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:35

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 1993' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:39 |

US3712308

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:35

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:39 |

US3712308

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:23:35

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:39 |

**US3712308**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 1993' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:39 |

**US3712308**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:39 |

**US3712308**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 1993' | System           | 26 Oct 2020 15:08:39 |

**US3712308**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '1993' | System           | 26 Oct 2020 15:08:39 |

**US3712308**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 1993' | System           | 26 Oct 2020 15:08:39 |

**US3712308**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '1993' | System           | 26 Oct 2020 15:08:39 |

US3712308

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:23:35

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0. | Coder Import (b) (4)  | 26 Oct 2020 15:22:15 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 26 Oct 2020 15:22:15 |
| Data point term sent to Coder  | System                | 26 Oct 2020 15:09:29 |
| User entered 'seasonal allergies'  | (b) (4), (b) (6)      | 26 Oct 2020 15:08:53 |

**US3712308**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2008' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:53 |

**US3712308**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:53 |

**US3712308**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:53 |

**US3712308**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:53 |

**US3712308**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:08:53 |

**US3712308**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2008' | System           | 26 Oct 2020 15:08:53 |

**US3712308**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2008' | System           | 26 Oct 2020 15:08:53 |

**US3712308**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:08:53 |

**US3712308**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:08:53 |

US3712308

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:23:35

[Condition](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4)           | 13 Feb 2021 20:45:03 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)     | 25 Jan 2021 12:09:41 |
| Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'updated' (Site from DM). | (b) (4), (b) (6)                | 22 Jan 2021 17:08:10 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).             | (b) (4), (b) (6)                | 15 Jan 2021 02:30:17 |
| User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 15:22:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 15:22:17 |
| Data point term sent to Coder   | System                          | 26 Oct 2020 15:09:31 |
| User entered 'hypertension'   | (b) (4), (b) (6)                | 26 Oct 2020 15:09:06 |

**US3712308**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2008' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:09:06 |

**US3712308**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:09:06 |

**US3712308**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:09:06 |

**US3712308**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:09:06 |

**US3712308**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:09:06 |

**US3712308**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2008' | System           | 26 Oct 2020 15:09:06 |

**US3712308**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2008' | System           | 26 Oct 2020 15:09:06 |

**US3712308**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:09:06 |

**US3712308**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:09:06 |

US3712308

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:35

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Bronchitis, LLT: Bronchitis - version MedDRA\\23.0. | Coder Import (b) (4)  | 26 Oct 2020 15:29:11 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 26 Oct 2020 15:29:11 |
| Data point term sent to Coder   | System                | 26 Oct 2020 15:12:35 |
| User entered 'occasional bronchitis'  | (b) (4), (b) (6)      | 26 Oct 2020 15:12:35 |

US3712308

Folder: Screening

Form: Medical History (6)

Generated On: 12 Aug 2021 13:23:35

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2010' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:12:35 |

**US3712308**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:12:35 |

**US3712308**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:12:35 |

**US3712308**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:12:35 |

**US3712308**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:12:35 |

**US3712308**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2010' | System           | 26 Oct 2020 15:12:35 |

**US3712308**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2010' | System           | 26 Oct 2020 15:12:35 |

**US3712308**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:12:35 |

**US3712308**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:12:35 |

US3712308

Folder: Screening

Form: Medical History (7)

Generated On: 12 Aug 2021 13:23:35

Condition

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)           | 13 Feb 2021 20:45:03 |
| User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)     | 25 Jan 2021 10:51:44 |
| Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'does not take medication for this condition ' (Site from DM). | (b) (4), (b) (6)                | 22 Jan 2021 17:09:12 |
| User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).  | (b) (4), (b) (6)                | 15 Jan 2021 02:31:17 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Bronchitis asthmatic - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 15:34:59 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.   | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 15:34:59 |
| Data point term sent to Coder  | System                          | 26 Oct 2020 15:13:36 |
| User entered 'bronchitis induced asthma'   | (b) (4), (b) (6)                | 26 Oct 2020 15:12:59 |

**US3712308**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2010' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:12:59 |

**US3712308**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:12:59 |

**US3712308**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:12:59 |

**US3712308**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:12:59 |

**US3712308**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:12:59 |

**US3712308**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2010' | System           | 26 Oct 2020 15:12:59 |

**US3712308**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2010' | System           | 26 Oct 2020 15:12:59 |

**US3712308**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:12:59 |

**US3712308**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:12:59 |

US3712308

Folder: Screening

Form: Medical History (8)

Generated On: 12 Aug 2021 13:23:35

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0. | Coder Import (b) (4)  | 26 Oct 2020 15:29:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 26 Oct 2020 15:29:54 |
| Data point term sent to Coder   | System                | 26 Oct 2020 15:13:38 |
| User entered 'hypothyroidism'   | (b) (4), (b) (6)      | 26 Oct 2020 15:13:11 |

**US3712308**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2010' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:11 |

**US3712308**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:11 |

**US3712308**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:11 |

**US3712308**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:11 |

**US3712308**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:11 |

**US3712308**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2010' | System           | 26 Oct 2020 15:13:11 |

**US3712308**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2010' | System           | 26 Oct 2020 15:13:11 |

**US3712308**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:13:11 |

**US3712308**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:13:11 |

US3712308

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:23:35

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0. | Coder Import (b) (4)  | 26 Oct 2020 15:29:56 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 26 Oct 2020 15:29:56 |
| Data point term sent to Coder   | System                | 26 Oct 2020 15:13:39 |
| User entered 'acid reflux'  | (b) (4), (b) (6)      | 26 Oct 2020 15:13:23 |

**US3712308**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2008' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:23 |

**US3712308**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:23 |

**US3712308**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:23 |

**US3712308**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:23 |

US3712308

Folder: Screening

Form: Medical History (9)

Generated On: 12 Aug 2021 13:23:35

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:23 |

**US3712308**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2008' | System           | 26 Oct 2020 15:13:23 |

**US3712308**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2008' | System           | 26 Oct 2020 15:13:23 |

**US3712308**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:13:23 |

**US3712308**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:13:23 |

US3712308

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:23:35

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Ankle fracture - version MedDRA\\23.0. | Coder Import (b) (4)  | 26 Oct 2020 15:31:35 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 26 Oct 2020 15:31:35 |
| Data point term sent to Coder  | System                | 26 Oct 2020 15:14:39 |
| User entered 'left ankle fracture'   | (b) (4), (b) (6)      | 26 Oct 2020 15:13:46 |

**US3712308**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2015' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:46 |

US3712308

Folder: Screening

Form: Medical History (10)

Generated On: 12 Aug 2021 13:23:35

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:46 |

**US3712308**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:46 |

**US3712308**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2015' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:46 |

**US3712308**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:46 |

**US3712308**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2015' | System           | 26 Oct 2020 15:13:46 |

**US3712308**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2015' | System           | 26 Oct 2020 15:13:46 |

**US3712308**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2015' | System           | 26 Oct 2020 15:13:46 |

**US3712308**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2015' | System           | 26 Oct 2020 15:13:46 |

US3712308

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:23:35

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Ankle operation, LLT: Ankle operation - version MedDRA\\23.0. | Coder Import (b) (4)  | 26 Oct 2020 15:31:35 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 26 Oct 2020 15:31:35 |
| Data point term sent to Coder  | System                | 26 Oct 2020 15:14:39 |
| User entered 'left ankle repair'   | (b) (4), (b) (6)      | 26 Oct 2020 15:13:58 |

**US3712308**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2015' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:58 |

US3712308

Folder: Screening

Form: Medical History (11)

Generated On: 12 Aug 2021 13:23:35

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:58 |

**US3712308**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:58 |

**US3712308**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2015' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:58 |

**US3712308**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:13:58 |

**US3712308**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2015' | System           | 26 Oct 2020 15:13:58 |

**US3712308**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2015' | System           | 26 Oct 2020 15:13:58 |

**US3712308**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2015' | System           | 26 Oct 2020 15:13:58 |

**US3712308**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2015' | System           | 26 Oct 2020 15:13:58 |

US3712308

Folder: Screening

Form: Medical History (12)

Generated On: 12 Aug 2021 13:23:35

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0. | Coder Import (b) (4)  | 26 Oct 2020 15:31:35 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 26 Oct 2020 15:31:35 |
| Data point term sent to Coder   | System                | 26 Oct 2020 15:14:40 |
| User entered 'migraines'  | (b) (4), (b) (6)      | 26 Oct 2020 15:14:12 |

**US3712308**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 1998' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:14:12 |

**US3712308**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:14:12 |

**US3712308**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:14:12 |

**US3712308**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:14:12 |

**US3712308**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:14:12 |

**US3712308**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 1998' | System           | 26 Oct 2020 15:14:12 |

**US3712308**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '1998' | System           | 26 Oct 2020 15:14:12 |

**US3712308**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:14:12 |

**US3712308**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:14:12 |

US3712308

Folder: Screening

Form: Medical History (13)

Generated On: 12 Aug 2021 13:23:35

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0. | Coder Import (b) (4)  | 26 Oct 2020 15:31:34 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 26 Oct 2020 15:31:34 |
| Data point term sent to Coder  | System                | 26 Oct 2020 15:14:40 |
| User entered 'anxiety'   | (b) (4), (b) (6)      | 26 Oct 2020 15:14:26 |

**US3712308**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2010' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:14:26 |

**US3712308**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:14:26 |

**US3712308**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:14:26 |

**US3712308**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:14:26 |

**US3712308**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:14:26 |

**US3712308**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2010' | System           | 26 Oct 2020 15:14:26 |

**US3712308**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2010' | System           | 26 Oct 2020 15:14:26 |

**US3712308**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:14:26 |

**US3712308**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:14:26 |

US3712308

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:23:35

Condition

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 16:44:08 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Breast prosthesis implantation - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 29 Mar 2021 12:59:17 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)  | 29 Mar 2021 12:59:17 |
| User signature succeeded.  | William Smith (b) (4)<br>(b) (4) | 13 Feb 2021 20:45:03 |
| User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Breast prosthesis user, LLT: Breast implant user - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)  | 26 Oct 2020 16:29:55 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)  | 26 Oct 2020 16:29:55 |
| Data point term sent to Coder  | System                           | 26 Oct 2020 15:16:43 |
| User entered 'breast implants placed'  | (b) (4), (b) (6)                 | 26 Oct 2020 15:15:49 |

US3712308

Folder: Screening

Form: Medical History (14)

Generated On: 12 Aug 2021 13:23:35

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2006' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:15:49 |

**US3712308**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:15:49 |

**US3712308**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:15:49 |

**US3712308**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2006' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:15:49 |

**US3712308**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:15:49 |

**US3712308**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2006' | System           | 26 Oct 2020 15:15:49 |

**US3712308**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2006' | System           | 26 Oct 2020 15:15:49 |

**US3712308**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2006' | System           | 26 Oct 2020 15:15:49 |

**US3712308**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2006' | System           | 26 Oct 2020 15:15:49 |

US3712308

Folder: Screening

Form: Medical History (15)

Generated On: 12 Aug 2021 13:23:35

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| 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. | Coder Import (b) (4)  | 26 Oct 2020 15:53:11 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 26 Oct 2020 15:53:11 |
| Data point term sent to Coder   | System                | 26 Oct 2020 15:25:01 |
| User entered 'obesity'  | (b) (4), (b) (6)      | 26 Oct 2020 15:24:13 |

**US3712308**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'un UNK 2019' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:24:13 |

**US3712308**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:24:13 |

**US3712308**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:23:35**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:24:13 |

**US3712308**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:23:35**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:24:13 |

**US3712308**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:23:35**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:24:13 |

**US3712308**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'Jan 2019' | System           | 26 Oct 2020 15:24:13 |

**US3712308**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '2019' | System           | 26 Oct 2020 15:24:13 |

**US3712308**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:24:13 |

**US3712308**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 15:24:13 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:27:45 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 26 Oct 2020 14:53:57 |

**US3712308**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4) | 13 Feb 2021 20:45:32 |
| DataPoint Verified.        | (b) (4), (b) (6)      | 10 Feb 2021 20:27:45 |
| User entered '23 Oct 2020' | (b) (4), (b) (6)      | 26 Oct 2020 14:53:57 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

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

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:27:45 |
| User closed query 'Data is required. Please provide.' (Site from System).             | System                      | 26 Oct 2020 15:06:10 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                      | 26 Oct 2020 15:06:10 |
| User entered '14:15' reason for change: Data Entry Error                              | (b) (4), (b) (6)            | 26 Oct 2020 15:06:10 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                      | 26 Oct 2020 14:53:57 |
| User entered empty.   | (b) (4), (b) (6)            | 26 Oct 2020 14:53:57 |

**US3712308**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '23 Oct 2020 14:15' | System           | 26 Oct 2020 15:06:10 |
| User entered empty.              | System           | 26 Oct 2020 14:53:57 |

**US3712308**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:27:45 |
| User entered '161.5' cm   | (b) (4), (b) (6)            | 26 Oct 2020 14:53:57 |
| DataPoint set to visible. | System                      | 23 Oct 2020 21:34:18 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:27:45 |
| User entered '89.1' kg    | (b) (4), (b) (6)            | 26 Oct 2020 14:53:57 |
| DataPoint set to visible. | System                      | 23 Oct 2020 21:34:18 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '34.16116'   | System           | 26 Oct 2020 14:53:57 |
| DataPoint set to visible. | System           | 23 Oct 2020 21:34:18 |

**US3712308**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'kg/m2'      | System           | 26 Oct 2020 14:53:57 |
| DataPoint set to visible. | System           | 23 Oct 2020 21:34:18 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

Temperature (xxx.x)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 20 Feb 2021 17:16:00 |
| User closed query 'Data is required. Please provide.' (Site from System).   | (b) (4)               | 18 Feb 2021 21:26:35 |
| Query 'Data is required. Please provide.' answered by data change (Site from System).   | System                | 18 Feb 2021 21:26:35 |
| User entered missing code ND - Not Done; reason for change Data Entry Error   | (b) (4), (b) (6)      | 18 Feb 2021 21:26:35 |
| User opened query 'Data is required. Please provide.' (Site from System).   | System                | 18 Feb 2021 21:26:24 |
| DataPoint Un-verified.  | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| Signature has been broken.  | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| User entered empty; reason for change Data Entry Error  | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:32 |
| DataPoint Verified.   | (b) (4), (b) (6)      | 10 Feb 2021 20:27:45 |
| User closed query 'per CDM RQ: per the CCGs, temperature, pulse, respiratory rate, SBP, and DBP should be ND if subject was screened, dosed, enrolled, and randomized on the same day for the screening visit' (Site from DM).  | (b) (4), (b) (6)      | 23 Nov 2020 21:48:05 |
| Query 'per CDM RQ: per the CCGs, temperature, pulse, respiratory rate, SBP, and DBP should be ND if subject was screened, dosed, enrolled, and randomized on the same day for the screening visit' answered with 'ht and wt at Vitals signs-dosing marked ND' (Site from DM). | (b) (4), (b) (6)      | 13 Nov 2020 14:59:40 |
| User opened query 'per CDM RQ: per the CCGs, temperature, pulse, respiratory rate, SBP, and DBP should be ND if subject was screened, dosed, enrolled, and randomized on the same day for the screening visit' (Site from DM).  | (b) (4), (b) (6)      | 12 Nov 2020 15:28:37 |
| Query 'per CDM RQ: per the CCGs, temperature, pulse, respiratory rate, SBP, and DBP should be ND for ' canceled (Site from DM).   | (b) (4), (b) (6)      | 12 Nov 2020 15:27:57 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

Temperature (xxx.x)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User opened query 'per CDM RQ: per the CCGs, temperature, pulse, respiratory rate, SBP, and DBP should be ND for ' (Site from DM).   | (b) (4), (b) (6) | 12 Nov 2020 15:27:54 |
| User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Kindly update as appropriate. ' (Site from DM).                                 | (b) (4), (b) (6) | 12 Nov 2020 15:27:54 |
| Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Kindly update as appropriate. ' answered with 'data updated at Day 1 visit' (Site from DM). | (b) (4), (b) (6) | 10 Nov 2020 20:57:44 |
| User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Kindly update as appropriate. ' (Site from DM).                                 | (b) (4), (b) (6) | 01 Nov 2020 08:18:30 |
| Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. ' canceled (Site from DM).  | (b) (4), (b) (6) | 01 Nov 2020 08:18:12 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

Temperature (xxx.x)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. <br />' (Site from DM). | (b) (4), (b) (6) | 01 Nov 2020 08:17:56 |
| User closed query 'Data is required. Please provide.' (Site from System).  | System           | 26 Oct 2020 15:06:10 |
| Query 'Data is required. Please provide.' answered by data change (Site from System).  | System           | 26 Oct 2020 15:06:10 |
| User entered '37.4' C reason for change: Data Entry Error  | (b) (4), (b) (6) | 26 Oct 2020 15:06:10 |
| User opened query 'Data is required. Please provide.' (Site from System).  | System           | 26 Oct 2020 14:53:57 |
| User entered empty.  | (b) (4), (b) (6) | 26 Oct 2020 14:53:57 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Route of measurement](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.                                      | William Smith (b) (4)       | 20 Feb 2021 17:16:00 |
| DataPoint Un-verified.   | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 21:26:24 |
| Signature has been broken.                                     | (b) (4), (b) (6)            | 18 Feb 2021 21:26:24 |
| User entered empty; reason for change Data Entry Error         | (b) (4), (b) (6)            | 18 Feb 2021 21:26:24 |
| User signature succeeded.                                      | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:27:45 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4), (b) (6)            | 26 Oct 2020 15:06:10 |
| User entered empty.  | (b) (4), (b) (6)            | 26 Oct 2020 14:53:57 |

**US3712308**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:27:45 |
| User entered empty.       | (b) (4), (b) (6)            | 26 Oct 2020 14:53:57 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Pulse \(xxx\)](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 20 Feb 2021 17:16:00 |
| User closed query 'Data is required. Please provide.' (Site from System).             | (b) (4)               | 18 Feb 2021 21:26:35 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                | 18 Feb 2021 21:26:35 |
| User entered missing code ND - Not Done; reason for change Data Entry Error           | (b) (4), (b) (6)      | 18 Feb 2021 21:26:35 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                | 18 Feb 2021 21:26:24 |
| DataPoint Un-verified.  | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| Signature has been broken.  | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| User entered empty; reason for change Data Entry Error                                | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:32 |
| DataPoint Verified.   | (b) (4)               | 10 Feb 2021 20:27:45 |
| User closed query 'Data is required. Please provide.' (Site from System).             | (b) (4), (b) (6)      | 26 Oct 2020 15:06:10 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                | 26 Oct 2020 15:06:10 |
| User entered '60' reason for change: Data Entry Error                                 | (b) (4), (b) (6)      | 26 Oct 2020 15:06:10 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                | 26 Oct 2020 14:53:57 |
| User entered empty.   | (b) (4), (b) (6)      | 26 Oct 2020 14:53:57 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'bpm'  | System           | 18 Feb 2021 21:26:35 |
| User entered empty. | System           | 18 Feb 2021 21:26:24 |
| User entered 'bpm'  | System           | 26 Oct 2020 15:06:10 |
| User entered empty. | System           | 26 Oct 2020 14:53:57 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

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

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 20 Feb 2021 17:16:00 |
| User closed query 'Data is required. Please provide.' (Site from System).             | (b) (4)               | 18 Feb 2021 21:26:35 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                | 18 Feb 2021 21:26:35 |
| User entered missing code ND - Not Done; reason for change Data Entry Error           | (b) (4), (b) (6)      | 18 Feb 2021 21:26:35 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                | 18 Feb 2021 21:26:24 |
| DataPoint Un-verified.  | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| Signature has been broken.  | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| User entered empty; reason for change Data Entry Error                                | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:32 |
| DataPoint Verified.   | (b) (4)               | 10 Feb 2021 20:27:45 |
| User closed query 'Data is required. Please provide.' (Site from System).             | (b) (4), (b) (6)      | 26 Oct 2020 15:06:10 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                | 26 Oct 2020 15:06:10 |
| User entered '16' reason for change: Data Entry Error                                 | (b) (4), (b) (6)      | 26 Oct 2020 15:06:10 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                | 26 Oct 2020 14:53:57 |
| User entered empty.   | (b) (4), (b) (6)      | 26 Oct 2020 14:53:57 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'breaths/min' | System           | 18 Feb 2021 21:26:35 |
| User entered empty.        | System           | 18 Feb 2021 21:26:24 |
| User entered 'breaths/min' | System           | 26 Oct 2020 15:06:10 |
| User entered empty.        | System           | 26 Oct 2020 14:53:57 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

Systolic Blood Pressure (xxx)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 20 Feb 2021 17:16:00 |
| User closed query 'Data is required. Please provide.' (Site from System).             | (b) (4)               | 18 Feb 2021 21:26:35 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                | 18 Feb 2021 21:26:35 |
| User entered missing code ND - Not Done; reason for change Data Entry Error           | (b) (4), (b) (6)      | 18 Feb 2021 21:26:35 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                | 18 Feb 2021 21:26:24 |
| DataPoint Un-verified.  | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| Signature has been broken.  | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| User entered empty; reason for change Data Entry Error                                | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:32 |
| DataPoint Verified.   | (b) (4)               | 10 Feb 2021 20:27:45 |
| User closed query 'Data is required. Please provide.' (Site from System).             | (b) (4), (b) (6)      | 26 Oct 2020 15:06:10 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                | 26 Oct 2020 15:06:10 |
| User entered '125' reason for change: Data Entry Error                                | (b) (4), (b) (6)      | 26 Oct 2020 15:06:10 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                | 26 Oct 2020 14:53:57 |
| User entered empty.   | (b) (4), (b) (6)      | 26 Oct 2020 14:53:57 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'mmHg' | System           | 18 Feb 2021 21:26:35 |
| User entered empty. | System           | 18 Feb 2021 21:26:24 |
| User entered 'mmHg' | System           | 26 Oct 2020 15:06:10 |
| User entered empty. | System           | 26 Oct 2020 14:53:57 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

Diastolic Blood Pressure (xxx)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 20 Feb 2021 17:16:00 |
| User closed query 'Data is required. Please provide.' (Site from System).             | (b) (4)               | 18 Feb 2021 21:26:35 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                | 18 Feb 2021 21:26:35 |
| User entered missing code ND - Not Done; reason for change Data Entry Error           | (b) (4), (b) (6)      | 18 Feb 2021 21:26:35 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                | 18 Feb 2021 21:26:24 |
| DataPoint Un-verified.  | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| Signature has been broken.  | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| User entered empty; reason for change Data Entry Error                                | (b) (4), (b) (6)      | 18 Feb 2021 21:26:24 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:32 |
| DataPoint Verified.   | (b) (4)               | 10 Feb 2021 20:27:45 |
| User closed query 'Data is required. Please provide.' (Site from System).             | (b) (4), (b) (6)      | 26 Oct 2020 15:06:10 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                | 26 Oct 2020 15:06:10 |
| User entered '79' reason for change: Data Entry Error                                 | (b) (4), (b) (6)      | 26 Oct 2020 15:06:10 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                | 26 Oct 2020 14:53:57 |
| User entered empty.   | (b) (4), (b) (6)      | 26 Oct 2020 14:53:57 |

US3712308

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'mmHg' | System           | 18 Feb 2021 21:26:35 |
| User entered empty. | System           | 18 Feb 2021 21:26:24 |
| User entered 'mmHg' | System           | 26 Oct 2020 15:06:10 |
| User entered empty. | System           | 26 Oct 2020 14:53:57 |

**US3712308**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
|                   |                  |                      |

**US3712308**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
|                   |                  |                      |

US3712308

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:35

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:06:23 |

**US3712308**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '23 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:06:23 |

US3712308

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '23 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:51:19 |

**US3712308**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:23:35**

[Is the participant of childbearing potential?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:51:19 |

**US3712308**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:23:35**

[If No, what is the reason?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:51:19 |

**US3712308**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:23:35**

[If Partner medically sterile or Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:51:19 |

**US3712308**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:51:19 |

**US3712308**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:23:35**

[Date of surgery unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:51:19 |

US3712308

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:51:19 |

**US3712308**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 12 Aug 2021 13:23:35**

[Date of last menstruation unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:51:19 |

US3712308

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

[Was the pregnancy test performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:53:34 |

US3712308

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

Date of test (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '23 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:53:34 |

US3712308

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

[Test performed](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.    | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Urine (URINE)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:53:34 |

**US3712308**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Result](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.          | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Negative (NEGATIVE)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:53:34 |

**US3712308**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Was FSH sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:53:34 |

**US3712308**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Collection date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:53:34 |

**US3712308**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Collection time](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 14:53:34 |

**US3712308**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty. | System           | 26 Oct 2020 14:53:34 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

[Specify](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.                    | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| DataPoint Verified.                          | (b) (4), (b) (6)      | 10 Feb 2021 20:29:07 |
| User entered 'funeral, restaurants and bars' | (b) (4), (b) (6)      | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

No Risk Identified

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.                            | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 18:59:10 |
| User entered '1'                                     | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 20:29:07 |
| User entered '0'          | (b) (4), (b) (6)      | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered '0'          | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered '0'          | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered '0'          | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

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

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User closed query 'Please review source and revise if needed. Does subject live in a Single Family Home, if so, the response needs to be checked.' (Site from CRA).             | (b) (4), (b) (6)      | 23 Feb 2021 23:01:00 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:03 |
| Query 'Please review source and revise if needed. Does subject live in a Single Family Home, if so, the response needs to be checked.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6)      | 12 Feb 2021 18:59:15 |
| DataPoint Un-verified.  | (b) (4), (b) (6)      | 12 Feb 2021 18:59:10 |
| User entered '1' reason for change: Data Entry Error  | (b) (4), (b) (6)      | 12 Feb 2021 18:59:10 |
| User opened query 'Please review source and revise if needed. Does subject live in a Single Family Home, if so, the response needs to be checked.' (Site from CRA).             | (b) (4), (b) (6)      | 10 Feb 2021 20:32:42 |
| DataPoint Verified.   | (b) (4), (b) (6)      | 10 Feb 2021 20:29:07 |
| User entered '0'  | (b) (4), (b) (6)      | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

[Other](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:05:40 |

US3712308

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:23:35

[Specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:29:07 |
| User entered empty.       | (b) (4), (b) (6)            | 26 Oct 2020 15:05:40 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Was this visit performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 23 Oct 2020 21:34:33 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '23 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 23 Oct 2020 21:34:33 |

US3712308

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:23:35

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.      | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 23 Oct 2020 21:34:33 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered 'VISIT1' | System           | 23 Oct 2020 21:34:33 |

US3712308

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:35

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

| Audit                      | User                             | Time (GMT)           |
|----------------------------|----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                 | 03 Apr 2021 08:35:14 |
| User signature succeeded.  | William Smith (b) (4)            | 13 Feb 2021 20:45:32 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6)      | 10 Feb 2021 20:33:45 |
| User entered '23 OCT 2020' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 23 Oct 2020 20:38:28 |

US3712308

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                             | Time (GMT)           |
|---------------------------|----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                 | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)            | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6)      | 10 Feb 2021 20:33:45 |
| User entered '118021'     | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 23 Oct 2020 20:38:28 |

US3712308

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:35

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

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                 | 03 Apr 2021 08:35:14 |
| User signature succeeded.                             | William Smith (b) (4)            | 13 Feb 2021 20:45:32 |
| DataPoint Verified.                                   | (b) (4)<br>(b) (4), (b) (6)      | 10 Feb 2021 20:33:45 |
| User entered '>=18 and <65 years and not at risk (1)' | RWS_ENDPOINT<br>ENDPOINT (b) (4) | 23 Oct 2020 20:38:28 |

US3712308

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:35

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)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:33:45 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 23 Oct 2020 21:34:46 |

US3712308

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:23:35

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)      | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 20:33:45 |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 23 Oct 2020 21:34:46 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:33:45 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 23 Oct 2020 21:34:46 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:23:35**

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4) | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 20:33:45 |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 23 Oct 2020 21:34:46 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:23:35**

[Liver Disease](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:33:45 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 23 Oct 2020 21:34:46 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:33:45 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 23 Oct 2020 21:34:46 |
| DataPoint set to visible. | System                      | 23 Oct 2020 21:34:14 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

Height

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.   | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User closed query 'per CDM RQ: drop down menu should be used to select ND for height/weight' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6) | 13 Nov 2020 20:20:40 |
| Query 'per CDM RQ: drop down menu should be used to select ND for height/weight' answered with 'ND entered manually. no dropdown option.' (Site from DM).   | (b) (4), (b) (6)            | 13 Nov 2020 14:54:38 |
| User entered missing code ND - Not Done; reason for change Data Entry Error   | (b) (4), (b) (6)            | 13 Nov 2020 14:54:18 |
| User opened query 'per CDM RQ: drop down menu should be used to select ND for height/weight' (Site from DM).  | (b) (4), (b) (6)            | 12 Nov 2020 15:15:30 |
| User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly. | (b) (4), (b) (6)            | 12 Nov 2020 15:15:30 |
| ' (Site from DM).   |                             |                      |
| Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.             | (b) (4), (b) (6)            | 10 Nov 2020 20:55:41 |
| ' answered with 'data updated ' (Site from DM).   |                             |                      |
| User entered empty; reason for change Data Entry Error  | (b) (4), (b) (6)            | 10 Nov 2020 20:55:35 |
| User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly. | (b) (4), (b) (6)            | 01 Nov 2020 08:17:12 |
| ' (Site from DM).   |                             |                      |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

Height

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| User entered '161.5' cm | (b) (4), (b) (6) | 26 Oct 2020 15:29:15 |
|                         |                  |                      |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

[Weight](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 03 Apr 2021 08:35:14 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:32 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)      | 13 Nov 2020 14:54:18 |
| User entered empty; reason for change Data Entry Error                      | (b) (4), (b) (6)      | 10 Nov 2020 20:55:35 |
| User entered '89.1' kg  | (b) (4), (b) (6)      | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

Height

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.   | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User closed query 'per CDM RQ: drop down menu should be used to select ND for height/weight' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6) | 13 Nov 2020 20:20:40 |
| Query 'per CDM RQ: drop down menu should be used to select ND for height/weight' answered with 'ND entered manually. no dropdown option.' (Site from DM).   | (b) (4), (b) (6)            | 13 Nov 2020 14:54:38 |
| User entered missing code ND - Not Done; reason for change Data Entry Error   | (b) (4), (b) (6)            | 13 Nov 2020 14:54:18 |
| User opened query 'per CDM RQ: drop down menu should be used to select ND for height/weight' (Site from DM).  | (b) (4), (b) (6)            | 12 Nov 2020 15:15:30 |
| User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly. | (b) (4), (b) (6)            | 12 Nov 2020 15:15:30 |
| ' (Site from DM).   |                             |                      |
| Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.             | (b) (4), (b) (6)            | 10 Nov 2020 20:55:41 |
| ' answered with 'data updated ' (Site from DM).   |                             |                      |
| User entered empty; reason for change Data Entry Error  | (b) (4), (b) (6)            | 10 Nov 2020 20:55:35 |
| User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly. | (b) (4), (b) (6)            | 01 Nov 2020 08:17:12 |
| ' (Site from DM).   |                             |                      |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

Height

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| User entered '161.5' cm | (b) (4), (b) (6) | 26 Oct 2020 15:29:15 |
|                         |                  |                      |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

[Weight](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 03 Apr 2021 08:35:14 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:32 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)      | 13 Nov 2020 14:54:18 |
| User entered empty; reason for change Data Entry Error                      | (b) (4), (b) (6)      | 10 Nov 2020 20:55:35 |
| User entered '89.1' kg  | (b) (4), (b) (6)      | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Were vital signs assessed?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                                  | William Smith (b) (4)       | 20 Feb 2021 17:16:00 |
| Signature has been broken.                                 | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 21:25:56 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4), (b) (6)            | 18 Feb 2021 21:25:56 |
| User signature succeeded.                                  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'No (N)'                                      | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

Date of assessment (*dd MMM yyyy*)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                                      | William Smith (b) (4)       | 20 Feb 2021 17:16:00 |
| Signature has been broken.                                     | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 21:25:56 |
| User entered '23 Oct 2020' reason for change: Data Entry Error | (b) (4), (b) (6)            | 18 Feb 2021 21:25:56 |
| User signature succeeded.                                      | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.  | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Time of assessment \(00:00-23:59\)](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                                | William Smith (b) (4)       | 20 Feb 2021 17:16:00 |
| Signature has been broken.                               | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 21:25:56 |
| User entered '14:15' reason for change: Data Entry Error | (b) (4), (b) (6)            | 18 Feb 2021 21:25:56 |
| User signature succeeded.                                | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.                                      | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered '23 Oct 2020 14:15' | System           | 18 Feb 2021 21:25:56 |
| User entered empty.              | System           | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

Temperature (xxx.x)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                                 | William Smith (b) (4)       | 20 Feb 2021 17:16:00 |
| Signature has been broken.                                | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 21:25:56 |
| User entered '37.4' C reason for change: Data Entry Error | (b) (4), (b) (6)            | 18 Feb 2021 21:25:56 |
| User signature succeeded.                                 | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.                                       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Route of measurement](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                                      | William Smith (b) (4)       | 20 Feb 2021 17:16:00 |
| Signature has been broken.                                     | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 21:25:56 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | (b) (4), (b) (6)            | 18 Feb 2021 21:25:56 |
| User signature succeeded.                                      | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.  | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Pulse \(xxx\)](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                             | William Smith (b) (4)       | 20 Feb 2021 17:16:00 |
| Signature has been broken.                            | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 21:25:56 |
| User entered '60' reason for change: Data Entry Error | (b) (4), (b) (6)            | 18 Feb 2021 21:25:56 |
| User signature succeeded.                             | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.                                   | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered 'bpm'  | System           | 18 Feb 2021 21:25:56 |
| User entered empty. | System           | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

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

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                             | William Smith (b) (4)       | 20 Feb 2021 17:16:00 |
| Signature has been broken.                            | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 21:25:56 |
| User entered '16' reason for change: Data Entry Error | (b) (4), (b) (6)            | 18 Feb 2021 21:25:56 |
| User signature succeeded.                             | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.                                   | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered 'breaths/min' | System           | 18 Feb 2021 21:25:56 |
| User entered empty.        | System           | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure \(xxx\)](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                              | William Smith (b) (4)       | 20 Feb 2021 17:16:00 |
| Signature has been broken.                             | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 21:25:56 |
| User entered '125' reason for change: Data Entry Error | (b) (4), (b) (6)            | 18 Feb 2021 21:25:56 |
| User signature succeeded.                              | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.                                    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered 'mmHg' | System           | 18 Feb 2021 21:25:56 |
| User entered empty. | System           | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

Diastolic Blood Pressure (xxx)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                             | William Smith (b) (4)       | 20 Feb 2021 17:16:00 |
| Signature has been broken.                            | (b) (4)<br>(b) (4), (b) (6) | 18 Feb 2021 21:25:56 |
| User entered '79' reason for change: Data Entry Error | (b) (4), (b) (6)            | 18 Feb 2021 21:25:56 |
| User signature succeeded.                             | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.                                   | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered 'mmHg' | System           | 18 Feb 2021 21:25:56 |
| User entered empty. | System           | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

Height

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.   | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User closed query 'per CDM RQ: drop down menu should be used to select ND for height/weight' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6) | 13 Nov 2020 20:20:40 |
| Query 'per CDM RQ: drop down menu should be used to select ND for height/weight' answered with 'ND entered manually. no dropdown option.' (Site from DM).   | (b) (4), (b) (6)            | 13 Nov 2020 14:54:38 |
| User entered missing code ND - Not Done; reason for change Data Entry Error   | (b) (4), (b) (6)            | 13 Nov 2020 14:54:18 |
| User opened query 'per CDM RQ: drop down menu should be used to select ND for height/weight' (Site from DM).  | (b) (4), (b) (6)            | 12 Nov 2020 15:15:30 |
| User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly. | (b) (4), (b) (6)            | 12 Nov 2020 15:15:30 |
| ' (Site from DM).   |                             |                      |
| Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.             | (b) (4), (b) (6)            | 10 Nov 2020 20:55:41 |
| ' answered with 'data updated ' (Site from DM).   |                             |                      |
| User entered empty; reason for change Data Entry Error  | (b) (4), (b) (6)            | 10 Nov 2020 20:55:35 |
| User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly. | (b) (4), (b) (6)            | 01 Nov 2020 08:17:12 |
| ' (Site from DM).   |                             |                      |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

Height

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| User entered '161.5' cm | (b) (4), (b) (6) | 26 Oct 2020 15:29:15 |
|                         |                  |                      |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

[Weight](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 03 Apr 2021 08:35:14 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:32 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | (b) (4), (b) (6)      | 13 Nov 2020 14:54:18 |
| User entered empty; reason for change Data Entry Error                      | (b) (4), (b) (6)      | 10 Nov 2020 20:55:35 |
| User entered '89.1' kg  | (b) (4), (b) (6)      | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '23 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Time of assessment \(00:00-23:59\)](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                                | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '17:57' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 16:15:48 |
| User entered '18:20'                                     | (b) (4), (b) (6)            | 26 Oct 2020 15:29:15 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered '23 Oct 2020 17:57' | System           | 26 Oct 2020 16:15:48 |
| User entered '23 Oct 2020 18:20' | System           | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '37.0' C     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '68'         | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered 'bpm' | System           | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '16'         | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered 'breaths/min' | System           | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '129'        | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered 'mmHg' | System           | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '87'         | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered 'mmHg' | System           | 26 Oct 2020 15:29:15 |

US3712308

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:35

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 16:18:23 |

US3712308

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:35

Date of examination (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 16:18:23 |

US3712308

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

[Was the pregnancy test performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:25:22 |

US3712308

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

Date of test (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:25:22 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Test performed](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:25:22 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Result](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:25:22 |

US3712308

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

[Was FSH sample collected?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 03 Apr 2021 08:35:14 |
| User signature succeeded.   | William Smith (b) (4) | 13 Feb 2021 20:45:32 |
| User closed query 'per CDM: please select yes or no for this field' (Site from DM).                   | (b) (4), (b) (6)      | 11 Nov 2020 13:42:58 |
| Query 'per CDM: please select yes or no for this field' answered with 'data updated ' (Site from DM). | (b) (4), (b) (6)      | 10 Nov 2020 20:56:36 |
| User entered 'No (N)' reason for change: Data Entry Error   | (b) (4), (b) (6)      | 10 Nov 2020 20:56:30 |
| User opened query 'per CDM: please select yes or no for this field' (Site from DM).                   | (b) (4), (b) (6)      | 04 Nov 2020 13:46:30 |
| User entered empty.   | (b) (4), (b) (6)      | 26 Oct 2020 15:25:22 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Collection date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:25:22 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Collection time](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:25:22 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered empty. | System           | 26 Oct 2020 15:25:22 |

US3712308

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[Was study treatment given?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:34:07 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 23 Oct 2020 21:35:08 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:23:35**

[If No, reason not given](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:34:07 |
| User entered empty.       | (b) (4), (b) (6)            | 23 Oct 2020 21:35:08 |

US3712308

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

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)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:34:07 |
| User entered empty.       | (b) (4), (b) (6)            | 23 Oct 2020 21:35:08 |

US3712308

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:34:07 |
| User entered '23 Oct 2020' | (b) (4), (b) (6)            | 23 Oct 2020 21:35:08 |

US3712308

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:34:07 |
| User entered '17:27'      | (b) (4), (b) (6)            | 23 Oct 2020 21:35:08 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered '23 Oct 2020 17:27' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[Which arm was used to give treatment?](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.          | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.                | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:34:07 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6)            | 23 Oct 2020 21:35:08 |

US3712308

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 20:34:07 |
| User entered 'ONCE' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered 'INTRAMUSCULAR' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:35

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 16:18:34 |

US3712308

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:35

Collection date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '23 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 16:18:34 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:23:35**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '14:44'      | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 16:18:34 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered '23 Oct 2020 14:44' | System           | 26 Oct 2020 16:18:34 |

US3712308

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:23:35

Collection date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '23 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 16:18:42 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 26 Oct 2020 16:18:42 |

US3712308

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:35

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 16:18:42 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '14:46'      | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 16:18:42 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered '23 Oct 2020 14:46' | System           | 26 Oct 2020 16:18:42 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 26 Oct 2020 16:18:42 |

US3712308

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:35

[Was the sample collected?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                                 | William Smith (b) (4)       | 26 Mar 2021 23:53:27 |
| Signature has been broken.                                | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 21:35:59 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6)            | 12 Mar 2021 21:35:59 |
| User signature succeeded.                                 | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'                                    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 16:18:42 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Collection time \(00:00 - 23:59\)](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                              | William Smith (b) (4)       | 26 Mar 2021 23:53:27 |
| Signature has been broken.                             | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 21:35:59 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)            | 12 Mar 2021 21:35:59 |
| User signature succeeded.                              | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '14:46'                                   | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 16:18:42 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered empty.              | System           | 12 Mar 2021 21:35:59 |
| User entered '23 Oct 2020 14:46' | System           | 26 Oct 2020 16:18:42 |

US3712308

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 16:18:44 |

**US3712308**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered '1'  | System           | 26 Oct 2020 16:18:44 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:16:24', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4d0ff6c0-9b3a-47de-a501-4ce7bf16a8d0' | System           | 23 Oct 2020 22:16:50 |
| User entered 'Yes (Y)'   | System           | 23 Oct 2020 22:16:50 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:16:31', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4d0ff6c0-9b3a-47de-a501-4ce7bf16a8d0' | System           | 23 Oct 2020 22:16:50 |
| User entered '98.6'  | System           | 23 Oct 2020 22:16:50 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:16:36', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4d0ff6c0-9b3a-47de-a501-4ce7bf16a8d0' | System           | 23 Oct 2020 22:16:50 |
| User entered 'No (N)'  | System           | 23 Oct 2020 22:16:50 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:16:47', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4d0ff6c0-9b3a-47de-a501-4ce7bf16a8d0' | System           | 23 Oct 2020 22:16:50 |
| User entered '23 Oct 2020 18:16'   | System           | 23 Oct 2020 22:16:50 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Oct 2020 17:47' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Oct 2020 20:17' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.                                | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 1, after vaccination (at home)' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:31:08', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8dcd1c4c-fbac-403a-927c-2d8b6efcd132' | System           | 24 Oct 2020 02:32:23 |
| User entered 'Yes (Y)'   | System           | 24 Oct 2020 02:32:23 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:32:06', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8dcd1c4c-fbac-403a-927c-2d8b6efcd132' | System           | 24 Oct 2020 02:32:23 |
| User entered '98.2'  | System           | 24 Oct 2020 02:32:23 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:32:11', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8dcd1c4c-fbac-403a-927c-2d8b6efcd132' | System           | 24 Oct 2020 02:32:23 |
| User entered 'No (N)'  | System           | 24 Oct 2020 02:32:23 |

**US3712308**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:32:20', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8dcd1c4c-fbac-403a-927c-2d8b6efcd132' | System           | 24 Oct 2020 02:32:23 |
| User entered '23 Oct 2020 22:32'   | System           | 24 Oct 2020 02:32:23 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Oct 2020 21:12' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '24 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 2' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:18:14', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '38ac09a1-9b8a-44bd-801c-07ca3d78b911' | System           | 24 Oct 2020 16:18:35 |
| User entered 'Yes (Y)'   | System           | 24 Oct 2020 16:18:35 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:18:19', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '38ac09a1-9b8a-44bd-801c-07ca3d78b911' | System           | 24 Oct 2020 16:18:35 |
| User entered '98.4'  | System           | 24 Oct 2020 16:18:35 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:18:22', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '38ac09a1-9b8a-44bd-801c-07ca3d78b911' | System           | 24 Oct 2020 16:18:35 |
| User entered 'No (N)'  | System           | 24 Oct 2020 16:18:35 |

**US3712308**

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

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:18:31', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '38ac09a1-9b8a-44bd-801c-07ca3d78b911' | System           | 24 Oct 2020 16:18:35 |
| User entered '24 Oct 2020 12:18'   | System           | 24 Oct 2020 16:18:35 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '24 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '25 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 3' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T17:08:57', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'c11ee877-78a5-49ba-b2d2-3e9b32cb4f25' | System           | 25 Oct 2020 21:11:14 |
| User entered 'Yes (Y)'   | System           | 25 Oct 2020 21:11:14 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T17:10:48', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'c11ee877-78a5-49ba-b2d2-3e9b32cb4f25' | System           | 25 Oct 2020 21:11:14 |
| User entered '97.5'  | System           | 25 Oct 2020 21:11:14 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T17:10:51', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'c11ee877-78a5-49ba-b2d2-3e9b32cb4f25' | System           | 25 Oct 2020 21:11:14 |
| User entered 'No (N)'  | System           | 25 Oct 2020 21:11:14 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T17:10:57', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'c11ee877-78a5-49ba-b2d2-3e9b32cb4f25' | System           | 25 Oct 2020 21:11:14 |
| User entered '25 Oct 2020 17:10'   | System           | 25 Oct 2020 21:11:14 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '25 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '26 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 4' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:19:58', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'a82f09b2-6a19-4d11-a9b3-d833fc2e8df0' | System           | 26 Oct 2020 16:20:11 |
| User entered 'Yes (Y)'   | System           | 26 Oct 2020 16:20:11 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:20:01', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'a82f09b2-6a19-4d11-a9b3-d833fc2e8df0' | System           | 26 Oct 2020 16:20:11 |
| User entered '98.3'  | System           | 26 Oct 2020 16:20:11 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:20:04', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'a82f09b2-6a19-4d11-a9b3-d833fc2e8df0' | System           | 26 Oct 2020 16:20:11 |
| User entered 'No (N)'  | System           | 26 Oct 2020 16:20:11 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:35

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:20:07', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'a82f09b2-6a19-4d11-a9b3-d833fc2e8df0' | System           | 26 Oct 2020 16:20:11 |
| User entered '26 Oct 2020 12:20'   | System           | 26 Oct 2020 16:20:11 |

**US3712308**

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

**Form: Temperature\_Day(4)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '26 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

**Form: Temperature\_Day(4)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '27 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 5' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:29:20', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'cc5c3d39-0364-4d75-b5cc-4ac71a91dbdf' | System           | 27 Oct 2020 16:30:24 |
| User entered 'Yes (Y)'   | System           | 27 Oct 2020 16:30:24 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:30:04', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'cc5c3d39-0364-4d75-b5cc-4ac71a91dbdf' | System           | 27 Oct 2020 16:30:24 |
| User entered '98.1'  | System           | 27 Oct 2020 16:30:24 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:30:08', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'cc5c3d39-0364-4d75-b5cc-4ac71a91dbdf' | System           | 27 Oct 2020 16:30:24 |
| User entered 'No (N)'  | System           | 27 Oct 2020 16:30:24 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:30:18', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'cc5c3d39-0364-4d75-b5cc-4ac71a91dbdf' | System           | 27 Oct 2020 16:30:24 |
| User entered '27 Oct 2020 12:30'   | System           | 27 Oct 2020 16:30:24 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '27 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '28 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 6' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:57:44', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8603bf6a-555c-45ad-a698-ba54229fb36c' | System           | 28 Oct 2020 18:58:01 |
| User entered 'Yes (Y)'   | System           | 28 Oct 2020 18:58:01 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:57:51', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8603bf6a-555c-45ad-a698-ba54229fb36c' | System           | 28 Oct 2020 18:58:01 |
| User entered '98.9'  | System           | 28 Oct 2020 18:58:01 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:57:54', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8603bf6a-555c-45ad-a698-ba54229fb36c' | System           | 28 Oct 2020 18:58:01 |
| User entered 'No (N)'  | System           | 28 Oct 2020 18:58:01 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:57:56', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8603bf6a-555c-45ad-a698-ba54229fb36c' | System           | 28 Oct 2020 18:58:01 |
| User entered '28 Oct 2020 14:57'   | System           | 28 Oct 2020 18:58:01 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '28 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '29 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 7' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:14:02', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '65b6f0b3-f1cc-4926-a797-ed9abd32e3d' | System           | 29 Oct 2020 17:14:45 |
| User entered 'Yes (Y)'  | System           | 29 Oct 2020 17:14:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:14:34', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '65b6f0b3-f1cc-4926-a797-ed9abd32e3d' | System           | 29 Oct 2020 17:14:45 |
| User entered '98.5'   | System           | 29 Oct 2020 17:14:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:14:37', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '65b6f0b3-f1cc-4926-a797-ed9abd32e3d' | System           | 29 Oct 2020 17:14:45 |
| User entered 'No (N)'   | System           | 29 Oct 2020 17:14:45 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:14:40', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '65b6f0b3-f1cc-4926-a797-ed9abd32e3d' | System           | 29 Oct 2020 17:14:45 |
| User entered '29 Oct 2020 13:14'  | System           | 29 Oct 2020 17:14:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '29 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:18:01', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '501f03a0-fd36-4e38-a884-9aa94a22a72e' | System           | 23 Oct 2020 22:18:18 |
| User entered 'None (1)'  | System           | 23 Oct 2020 22:18:18 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:18:04', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '501f03a0-fd36-4e38-a884-9aa94a22a72e' | System           | 23 Oct 2020 22:18:18 |
| User entered 'No (N)'  | System           | 23 Oct 2020 22:18:18 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:18:07', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '501f03a0-fd36-4e38-a884-9aa94a22a72e' | System           | 23 Oct 2020 22:18:18 |
| User entered 'No (N)'  | System           | 23 Oct 2020 22:18:18 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:18:11', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '501f03a0-fd36-4e38-a884-9aa94a22a72e' | System           | 23 Oct 2020 22:18:18 |
| User entered 'None (1)'  | System           | 23 Oct 2020 22:18:18 |

**US3712308**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:18:15', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '501f03a0-fd36-4e38-a884-9aa94a22a72e' | System           | 23 Oct 2020 22:18:18 |
| User entered '23 Oct 2020 18:18'   | System           | 23 Oct 2020 22:18:18 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Oct 2020 17:47' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Oct 2020 20:17' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.                                | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 1, after vaccination (at home)' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:32:31', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ac415b2c-0658-4599-9cc6-ee7def10ece9' | System           | 24 Oct 2020 02:32:57 |
| User entered 'None (1)'  | System           | 24 Oct 2020 02:32:57 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:32:37', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ac415b2c-0658-4599-9cc6-ee7def10ece9' | System           | 24 Oct 2020 02:32:57 |
| User entered 'No (N)'  | System           | 24 Oct 2020 02:32:57 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:32:44', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ac415b2c-0658-4599-9cc6-ee7def10ece9' | System           | 24 Oct 2020 02:32:57 |
| User entered 'No (N)'  | System           | 24 Oct 2020 02:32:57 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:32:51', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ac415b2c-0658-4599-9cc6-ee7def10ece9' | System           | 24 Oct 2020 02:32:57 |
| User entered 'None (1)'  | System           | 24 Oct 2020 02:32:57 |

**US3712308**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:32:54', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ac415b2c-0658-4599-9cc6-ee7def10ece9' | System           | 24 Oct 2020 02:32:57 |
| User entered '23 Oct 2020 22:32'   | System           | 24 Oct 2020 02:32:57 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Oct 2020 21:12' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '24 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 2' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:18:38', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fbbb9571-2341-45fe-9d4f-407275529a50' | System           | 24 Oct 2020 16:18:57 |
| User entered 'None (1)'  | System           | 24 Oct 2020 16:18:57 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:18:42', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fbbb9571-2341-45fe-9d4f-407275529a50' | System           | 24 Oct 2020 16:18:57 |
| User entered 'No (N)'  | System           | 24 Oct 2020 16:18:57 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:18:48', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fbbb9571-2341-45fe-9d4f-407275529a50' | System           | 24 Oct 2020 16:18:57 |
| User entered 'No (N)'  | System           | 24 Oct 2020 16:18:57 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:18:50', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fbbb9571-2341-45fe-9d4f-407275529a50' | System           | 24 Oct 2020 16:18:57 |
| User entered 'None (1)'  | System           | 24 Oct 2020 16:18:57 |

**US3712308**

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

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:18:53', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fbbb9571-2341-45fe-9d4f-407275529a50' | System           | 24 Oct 2020 16:18:57 |
| User entered '24 Oct 2020 12:18'   | System           | 24 Oct 2020 16:18:57 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '24 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '25 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 3' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T16:43:04', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'bda4de93-370f-450b-bc9f-50cbb655afb9' | System           | 25 Oct 2020 20:43:23 |
| User entered 'None (1)'  | System           | 25 Oct 2020 20:43:23 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T16:43:08', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'bda4de93-370f-450b-bc9f-50cbb655afb9' | System           | 25 Oct 2020 20:43:23 |
| User entered 'No (N)'  | System           | 25 Oct 2020 20:43:23 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T16:43:10', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'bda4de93-370f-450b-bc9f-50cbb655afb9' | System           | 25 Oct 2020 20:43:23 |
| User entered 'No (N)'  | System           | 25 Oct 2020 20:43:23 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T16:43:16', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'bda4de93-370f-450b-bc9f-50cbb655afb9' | System           | 25 Oct 2020 20:43:23 |
| User entered 'None (1)'  | System           | 25 Oct 2020 20:43:23 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T16:43:19', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'bda4de93-370f-450b-bc9f-50cbb655afb9' | System           | 25 Oct 2020 20:43:23 |
| User entered '25 Oct 2020 16:43'   | System           | 25 Oct 2020 20:43:23 |

**US3712308**

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

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '25 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '26 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 4' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:14:30', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd2e81cb6-a5b7-4f57-abb-b-e83283513ec8' | System           | 26 Oct 2020 16:14:51 |
| User entered 'Does not interfere with activity (2)'   | System           | 26 Oct 2020 16:14:51 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:14:32', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd2e81cb6-a5b7-4f57-abbb-e83283513ec8' | System           | 26 Oct 2020 16:14:51 |
| User entered 'No (N)'  | System           | 26 Oct 2020 16:14:51 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:14:39', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd2e81cb6-a5b7-4f57-abb-b-e83283513ec8' | System           | 26 Oct 2020 16:14:51 |
| User entered 'No (N)'   | System           | 26 Oct 2020 16:14:51 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:14:43', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd2e81cb6-a5b7-4f57-abbb-e83283513ec8' | System           | 26 Oct 2020 16:14:51 |
| User entered 'None (1)'  | System           | 26 Oct 2020 16:14:51 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:14:45', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd2e81cb6-a5b7-4f57-abb-b-e83283513ec8' | System           | 26 Oct 2020 16:14:51 |
| User entered '26 Oct 2020 12:14'  | System           | 26 Oct 2020 16:14:51 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '26 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '27 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 5' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:27:08', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '43babdbc-2324-4c98-a2d5-2d58cf636871' | System           | 27 Oct 2020 16:27:26 |
| User entered 'Does not interfere with activity (2)'  | System           | 27 Oct 2020 16:27:26 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:35

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:27:11', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '43babdbc-2324-4c98-a2d5-2d58cf636871' | System           | 27 Oct 2020 16:27:26 |
| User entered 'No (N)'  | System           | 27 Oct 2020 16:27:26 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:27:16', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '43babdbc-2324-4c98-a2d5-2d58cf636871' | System           | 27 Oct 2020 16:27:26 |
| User entered 'No (N)'  | System           | 27 Oct 2020 16:27:26 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:27:20', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '43babdbc-2324-4c98-a2d5-2d58cf636871' | System           | 27 Oct 2020 16:27:26 |
| User entered 'None (1)'  | System           | 27 Oct 2020 16:27:26 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:35

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:27:23', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '43babdbc-2324-4c98-a2d5-2d58cf636871' | System           | 27 Oct 2020 16:27:26 |
| User entered '27 Oct 2020 12:27'   | System           | 27 Oct 2020 16:27:26 |

**US3712308**

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

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '27 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '28 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 6' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:58:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '085de7af-90f1-42a2-a92c-2b6c85cc788d' | System           | 28 Oct 2020 18:58:40 |
| User entered 'None (1)'  | System           | 28 Oct 2020 18:58:40 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:58:03', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '085de7af-90f1-42a2-a92c-2b6c85cc788d' | System           | 28 Oct 2020 18:58:40 |
| User entered 'No (N)'  | System           | 28 Oct 2020 18:58:40 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:58:06', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '085de7af-90f1-42a2-a92c-2b6c85cc788d' | System           | 28 Oct 2020 18:58:40 |
| User entered 'No (N)'  | System           | 28 Oct 2020 18:58:40 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:58:10', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '085de7af-90f1-42a2-a92c-2b6c85cc788d' | System           | 28 Oct 2020 18:58:40 |
| User entered 'None (1)'  | System           | 28 Oct 2020 18:58:40 |

**US3712308**

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

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:58:13', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '085de7af-90f1-42a2-a92c-2b6c85cc788d' | System           | 28 Oct 2020 18:58:40 |
| User entered '28 Oct 2020 14:58'   | System           | 28 Oct 2020 18:58:40 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '28 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '29 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 7' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:11:55', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'cac35eb6-9e76-4f3f-a68f-6df2ed6114d9' | System           | 29 Oct 2020 17:12:16 |
| User entered 'None (1)'  | System           | 29 Oct 2020 17:12:16 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:11:57', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'cac35eb6-9e76-4f3f-a68f-6df2ed6114d9' | System           | 29 Oct 2020 17:12:16 |
| User entered 'No (N)'  | System           | 29 Oct 2020 17:12:16 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:12:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'cac35eb6-9e76-4f3f-a68f-6df2ed6114d9' | System           | 29 Oct 2020 17:12:16 |
| User entered 'No (N)'  | System           | 29 Oct 2020 17:12:16 |

US3712308

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:12:03', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'cac35eb6-9e76-4f3f-a68f-6df2ed6114d9' | System           | 29 Oct 2020 17:12:16 |
| User entered 'None (1)'  | System           | 29 Oct 2020 17:12:16 |

**US3712308**

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

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:12:06', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'cac35eb6-9e76-4f3f-a68f-6df2ed6114d9' | System           | 29 Oct 2020 17:12:16 |
| User entered '29 Oct 2020 13:12'   | System           | 29 Oct 2020 17:12:16 |

**US3712308**

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

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '29 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:18:27', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '85e10322-c7ea-41eb-881a-0bcdaf2451ac' | System           | 23 Oct 2020 22:18:52 |
| User entered 'None (0)'  | System           | 23 Oct 2020 22:18:52 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:18:30', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '85e10322-c7ea-41eb-881a-0bcdaf2451ac' | System           | 23 Oct 2020 22:18:52 |
| User entered 'None (0)'  | System           | 23 Oct 2020 22:18:52 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:18:32', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '85e10322-c7ea-41eb-881a-0bcdaf2451ac' | System           | 23 Oct 2020 22:18:52 |
| User entered 'None (0)'  | System           | 23 Oct 2020 22:18:52 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:18:35', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '85e10322-c7ea-41eb-881a-0bcdaf2451ac' | System           | 23 Oct 2020 22:18:52 |
| User entered 'None (0)'  | System           | 23 Oct 2020 22:18:52 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:18:37', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '85e10322-c7ea-41eb-881a-0bcdaf2451ac' | System           | 23 Oct 2020 22:18:52 |
| User entered 'None (0)'  | System           | 23 Oct 2020 22:18:52 |

**US3712308**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:23:35**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:18:39', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '85e10322-c7ea-41eb-881a-0bcdaf2451ac' | System           | 23 Oct 2020 22:18:52 |
| User entered 'None (0)'  | System           | 23 Oct 2020 22:18:52 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:18:44', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '85e10322-c7ea-41eb-881a-0bcdaf2451ac' | System           | 23 Oct 2020 22:18:52 |
| User entered 'No (N)'  | System           | 23 Oct 2020 22:18:52 |

**US3712308**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T18:18:49', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '85e10322-c7ea-41eb-881a-0bcdaf2451ac' | System           | 23 Oct 2020 22:18:52 |
| User entered '23 Oct 2020 18:18'   | System           | 23 Oct 2020 22:18:52 |

**US3712308**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Oct 2020 17:47' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Oct 2020 20:17' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.                                | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 1, after vaccination (at home)' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:23:35**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:33:21', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'de0842c7-925d-4199-a28a-25eb29d2e36a' | System           | 24 Oct 2020 02:33:30 |
| User entered 'No interference with activity (1)'   | System           | 24 Oct 2020 02:33:30 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:33:01', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'de0842c7-925d-4199-a28a-25eb29d2e36a' | System           | 24 Oct 2020 02:33:30 |
| User entered 'None (0)'  | System           | 24 Oct 2020 02:33:30 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:33:03', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'de0842c7-925d-4199-a28a-25eb29d2e36a' | System           | 24 Oct 2020 02:33:30 |
| User entered 'None (0)'  | System           | 24 Oct 2020 02:33:30 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:33:06', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'de0842c7-925d-4199-a28a-25eb29d2e36a' | System           | 24 Oct 2020 02:33:30 |
| User entered 'None (0)'  | System           | 24 Oct 2020 02:33:30 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:33:09', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'de0842c7-925d-4199-a28a-25eb29d2e36a' | System           | 24 Oct 2020 02:33:30 |
| User entered 'None (0)'  | System           | 24 Oct 2020 02:33:30 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:33:11', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'de0842c7-925d-4199-a28a-25eb29d2e36a' | System           | 24 Oct 2020 02:33:30 |
| User entered 'None (0)'  | System           | 24 Oct 2020 02:33:30 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:33:17', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'de0842c7-925d-4199-a28a-25eb29d2e36a' | System           | 24 Oct 2020 02:33:30 |
| User entered 'No (N)'  | System           | 24 Oct 2020 02:33:30 |

**US3712308**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-23T22:33:23', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'de0842c7-925d-4199-a28a-25eb29d2e36a' | System           | 24 Oct 2020 02:33:30 |
| User entered '23 Oct 2020 22:33'   | System           | 24 Oct 2020 02:33:30 |

**US3712308**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Oct 2020 21:12' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '24 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 2' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:18:58', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e4dde3ee-7125-403f-a5b3-5777b03892f4' | System           | 24 Oct 2020 16:19:25 |
| User entered 'No interference with activity (1)'   | System           | 24 Oct 2020 16:19:25 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:19:03', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e4dde3ee-7125-403f-a5b3-5777b03892f4' | System           | 24 Oct 2020 16:19:25 |
| User entered 'None (0)'  | System           | 24 Oct 2020 16:19:25 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:19:05', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e4dde3ee-7125-403f-a5b3-5777b03892f4' | System           | 24 Oct 2020 16:19:25 |
| User entered 'None (0)'  | System           | 24 Oct 2020 16:19:25 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:19:07', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e4dde3ee-7125-403f-a5b3-5777b03892f4' | System           | 24 Oct 2020 16:19:25 |
| User entered 'None (0)'  | System           | 24 Oct 2020 16:19:25 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:19:09', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e4dde3ee-7125-403f-a5b3-5777b03892f4' | System           | 24 Oct 2020 16:19:25 |
| User entered 'None (0)'  | System           | 24 Oct 2020 16:19:25 |

**US3712308**

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

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:19:12', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e4dde3ee-7125-403f-a5b3-5777b03892f4' | System           | 24 Oct 2020 16:19:25 |
| User entered 'None (0)'  | System           | 24 Oct 2020 16:19:25 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:19:15', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e4dde3ee-7125-403f-a5b3-5777b03892f4' | System           | 24 Oct 2020 16:19:25 |
| User entered 'No (N)'  | System           | 24 Oct 2020 16:19:25 |

**US3712308**

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

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-24T12:19:20', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e4dde3ee-7125-403f-a5b3-5777b03892f4' | System           | 24 Oct 2020 16:19:25 |
| User entered '24 Oct 2020 12:19'   | System           | 24 Oct 2020 16:19:25 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '24 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '25 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 3' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T16:43:24', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '262025e6-1c7c-430e-be51-b8c49cf4c1d4' | System           | 25 Oct 2020 20:44:01 |
| User entered 'None (0)'  | System           | 25 Oct 2020 20:44:01 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T16:43:26', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '262025e6-1c7c-430e-be51-b8c49cf4c1d4' | System           | 25 Oct 2020 20:44:01 |
| User entered 'None (0)'  | System           | 25 Oct 2020 20:44:01 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T16:43:28', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '262025e6-1c7c-430e-be51-b8c49cf4c1d4' | System           | 25 Oct 2020 20:44:01 |
| User entered 'None (0)'  | System           | 25 Oct 2020 20:44:01 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T16:43:30', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '262025e6-1c7c-430e-be51-b8c49cf4c1d4' | System           | 25 Oct 2020 20:44:01 |
| User entered 'None (0)'  | System           | 25 Oct 2020 20:44:01 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T16:43:32', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '262025e6-1c7c-430e-be51-b8c49cf4c1d4' | System           | 25 Oct 2020 20:44:01 |
| User entered 'None (0)'  | System           | 25 Oct 2020 20:44:01 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T16:43:34', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '262025e6-1c7c-430e-be51-b8c49cf4c1d4' | System           | 25 Oct 2020 20:44:01 |
| User entered 'None (0)'  | System           | 25 Oct 2020 20:44:01 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T16:43:36', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '262025e6-1c7c-430e-be51-b8c49cf4c1d4' | System           | 25 Oct 2020 20:44:01 |
| User entered 'No (N)'  | System           | 25 Oct 2020 20:44:01 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-25T16:43:58', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '262025e6-1c7c-430e-be51-b8c49cf4c1d4' | System           | 25 Oct 2020 20:44:01 |
| User entered '25 Oct 2020 16:43'   | System           | 25 Oct 2020 20:44:01 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '25 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '26 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 4' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:14:48', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'be74aeda-902d-405a-9ed9-b65aab25202f' User entered 'None (0)' | System           | 26 Oct 2020 16:15:10 |
|  | System           | 26 Oct 2020 16:15:10 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:14:50', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'be74aeda-902d-405a-9ed9-b65aab25202f' User entered 'None (0)' | System           | 26 Oct 2020 16:15:10 |
|  | System           | 26 Oct 2020 16:15:10 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:14:52', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'be74aeda-902d-405a-9ed9-b65aab25202f' User entered 'None (0)' | System           | 26 Oct 2020 16:15:10 |
|  | System           | 26 Oct 2020 16:15:10 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:14:54', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'be74aeda-902d-405a-9ed9-b65aab25202f' | System           | 26 Oct 2020 16:15:10 |
| User entered 'None (0)'  | System           | 26 Oct 2020 16:15:10 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:14:55', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'be74aeda-902d-405a-9ed9-b65aab25202f' | System           | 26 Oct 2020 16:15:10 |
| User entered 'None (0)'  | System           | 26 Oct 2020 16:15:10 |

**US3712308**

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

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:23:35**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:14:57', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'be74aeda-902d-405a-9ed9-b65aab25202f' User entered 'None (0)' | System           | 26 Oct 2020 16:15:10 |
|  | System           | 26 Oct 2020 16:15:10 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:15:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'be74aeda-902d-405a-9ed9-b65aab25202f' | System           | 26 Oct 2020 16:15:10 |
| User entered 'No (N)'  | System           | 26 Oct 2020 16:15:10 |

**US3712308**

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

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-26T12:15:03', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'be74aeda-902d-405a-9ed9-b65aab25202f' User entered '26 Oct 2020 12:15' | System           | 26 Oct 2020 16:15:10 |
|   | System           | 26 Oct 2020 16:15:10 |

**US3712308**

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

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '26 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '27 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 5' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:27:30', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd4507e97-16bc-47b4-87a1-98130f5bb57c' | System           | 27 Oct 2020 16:28:10 |
| User entered 'No interference with activity (1)'   | System           | 27 Oct 2020 16:28:10 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:27:37', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd4507e97-16bc-47b4-87a1-98130f5bb57c' | System           | 27 Oct 2020 16:28:10 |
| User entered 'Some interference with activity (2)'   | System           | 27 Oct 2020 16:28:10 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:27:42', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd4507e97-16bc-47b4-87a1-98130f5bb57c' | System           | 27 Oct 2020 16:28:10 |
| User entered 'None (0)'  | System           | 27 Oct 2020 16:28:10 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:27:44', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd4507e97-16bc-47b4-87a1-98130f5bb57c' | System           | 27 Oct 2020 16:28:10 |
| User entered 'None (0)'  | System           | 27 Oct 2020 16:28:10 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:27:51', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd4507e97-16bc-47b4-87a1-98130f5bb57c' | System           | 27 Oct 2020 16:28:10 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System           | 27 Oct 2020 16:28:10 |

**US3712308**

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

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:27:54', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd4507e97-16bc-47b4-87a1-98130f5bb57c' | System           | 27 Oct 2020 16:28:10 |
| User entered 'None (0)'  | System           | 27 Oct 2020 16:28:10 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:28:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd4507e97-16bc-47b4-87a1-98130f5bb57c' | System           | 27 Oct 2020 16:28:10 |
| User entered 'No (N)'  | System           | 27 Oct 2020 16:28:10 |

**US3712308**

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

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-27T12:28:03', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd4507e97-16bc-47b4-87a1-98130f5bb57c' | System           | 27 Oct 2020 16:28:10 |
| User entered '27 Oct 2020 12:28'   | System           | 27 Oct 2020 16:28:10 |

**US3712308**

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

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '27 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '28 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 6' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:58:17', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3ebd13f4-dbc0-4c89-92a8-cf3733b87d27' | System           | 28 Oct 2020 18:58:50 |
| User entered 'None (0)'  | System           | 28 Oct 2020 18:58:50 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:58:21', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3ebd13f4-dbc0-4c89-92a8-cf3733b87d27' | System           | 28 Oct 2020 18:58:50 |
| User entered 'No interference with activity (1)'   | System           | 28 Oct 2020 18:58:50 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:58:24', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3ebd13f4-dbc0-4c89-92a8-cf3733b87d27' | System           | 28 Oct 2020 18:58:50 |
| User entered 'None (0)'  | System           | 28 Oct 2020 18:58:50 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:58:27', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3ebd13f4-dbc0-4c89-92a8-cf3733b87d27' | System           | 28 Oct 2020 18:58:50 |
| User entered 'None (0)'  | System           | 28 Oct 2020 18:58:50 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:58:29', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3ebd13f4-dbc0-4c89-92a8-cf3733b87d27' | System           | 28 Oct 2020 18:58:50 |
| User entered 'None (0)'  | System           | 28 Oct 2020 18:58:50 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:58:32', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3ebd13f4-dbc0-4c89-92a8-cf3733b87d27' | System           | 28 Oct 2020 18:58:50 |
| User entered 'None (0)'  | System           | 28 Oct 2020 18:58:50 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:58:36', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3ebd13f4-dbc0-4c89-92a8-cf3733b87d27' | System           | 28 Oct 2020 18:58:50 |
| User entered 'No (N)'  | System           | 28 Oct 2020 18:58:50 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-28T14:58:40', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3ebd13f4-dbc0-4c89-92a8-cf3733b87d27' | System           | 28 Oct 2020 18:58:50 |
| User entered '28 Oct 2020 14:58'   | System           | 28 Oct 2020 18:58:50 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '28 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '29 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Oct 2020 21:35:08 |
| User entered 'Day 7' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:12:12', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fee1ca68-9400-491e-a390-4a0ddd83f745' | System           | 29 Oct 2020 17:12:45 |
| User entered 'No interference with activity (1)'   | System           | 29 Oct 2020 17:12:45 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:12:16', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fee1ca68-9400-491e-a390-4a0ddd83f745' | System           | 29 Oct 2020 17:12:45 |
| User entered 'Some interference with activity (2)'   | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:12:20', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fee1ca68-9400-491e-a390-4a0ddd83f745' | System           | 29 Oct 2020 17:12:45 |
| User entered 'No interference with activity (1)'   | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:12:23', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fee1ca68-9400-491e-a390-4a0ddd83f745' | System           | 29 Oct 2020 17:12:45 |
| User entered 'No interference with activity (1)'   | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:12:33', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fee1ca68-9400-491e-a390-4a0ddd83f745' | System           | 29 Oct 2020 17:12:45 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System           | 29 Oct 2020 17:12:45 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:12:35', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fee1ca68-9400-491e-a390-4a0ddd83f745' | System           | 29 Oct 2020 17:12:45 |
| User entered 'None (0)'  | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:12:37', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fee1ca68-9400-491e-a390-4a0ddd83f745' | System           | 29 Oct 2020 17:12:45 |
| User entered 'No (N)'  | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-29T13:12:39', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fee1ca68-9400-491e-a390-4a0ddd83f745' | System           | 29 Oct 2020 17:12:45 |
| User entered '29 Oct 2020 13:12'   | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '29 Oct 2020 12:00' | System           | 23 Oct 2020 21:35:08 |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Oct 2020 11:59' | System           | 23 Oct 2020 21:35:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 29 Oct 2020 17:12:45 |
| User entered 'Day 8' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-30T15:05:32', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '14d98487-9481-4dff-93cc-84044b67c5db' | System           | 30 Oct 2020 19:05:41 |
| User entered 'No interference with activity (1)'   | System           | 30 Oct 2020 19:05:41 |

**US3712308**

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

**Form: Headache\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-30T15:05:36', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '14d98487-9481-4dff-93cc-84044b67c5db' | System           | 30 Oct 2020 19:05:41 |
| User entered '30 Oct 2020 15:05'   | System           | 30 Oct 2020 19:05:41 |

**US3712308**

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

**Form: Headache\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Oct 2020 12:00' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '31 Oct 2020 11:59' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 29 Oct 2020 17:12:45 |
| User entered 'Day 9' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-31T14:20:50', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd65a8375-4ceb-4153-a2b2-7315b59c2933' | System           | 31 Oct 2020 18:20:57 |
| User entered 'No interference with activity (1)'   | System           | 31 Oct 2020 18:20:57 |

**US3712308**

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

**Form: Headache\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-31T14:20:55', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd65a8375-4ceb-4153-a2b2-7315b59c2933' | System           | 31 Oct 2020 18:20:57 |
| User entered '31 Oct 2020 14:20'   | System           | 31 Oct 2020 18:20:57 |

**US3712308**

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

**Form: Headache\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '31 Oct 2020 12:00' | System           | 29 Oct 2020 17:12:45 |

**US3712308**

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

**Form: Headache\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '01 Nov 2020 11:59' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 30 Oct 2020 19:05:41 |
| User entered 'Day 10' | System           | 30 Oct 2020 19:05:41 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-01T13:32:07', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '771ce9b4-d5f5-4a0d-a09c-cacbce03d445' | System           | 01 Nov 2020 18:32:15 |
| User entered 'No interference with activity (1)'   | System           | 01 Nov 2020 18:32:15 |

**US3712308**

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

**Form: Headache\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-01T13:32:09', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '771ce9b4-d5f5-4a0d-a09c-cacbce03d445' | System           | 01 Nov 2020 18:32:15 |
| User entered '01 Nov 2020 13:32'   | System           | 01 Nov 2020 18:32:15 |

**US3712308**

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

**Form: Headache\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '01 Nov 2020 12:00' | System           | 30 Oct 2020 19:05:41 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '02 Nov 2020 11:59' | System           | 30 Oct 2020 19:05:41 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 31 Oct 2020 18:20:57 |
| User entered 'Day 11' | System           | 31 Oct 2020 18:20:57 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-02T12:15:16', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd3002424-8e63-4726-ba9f-d792f454c50c' | System           | 02 Nov 2020 17:15:24 |
| User entered 'No interference with activity (1)'   | System           | 02 Nov 2020 17:15:24 |

**US3712308**

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

**Form: Headache\_Day(11)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-02T12:15:18', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd3002424-8e63-4726-ba9f-d792f454c50c' | System           | 02 Nov 2020 17:15:24 |
| User entered '02 Nov 2020 12:15'   | System           | 02 Nov 2020 17:15:24 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '02 Nov 2020 12:00' | System           | 31 Oct 2020 18:20:57 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(11)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '03 Nov 2020 11:59' | System           | 31 Oct 2020 18:20:57 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 01 Nov 2020 18:32:15 |
| User entered 'Day 12' | System           | 01 Nov 2020 18:32:15 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(12)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-03T12:10:20', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '077bf6c2-b4d8-4a6e-b422-f2b27ffa81de' | System           | 03 Nov 2020 17:10:27 |
| User entered 'No interference with activity (1)'   | System           | 03 Nov 2020 17:10:27 |

**US3712308**

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

**Form: Headache\_Day(12)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-03T12:10:22', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '077bf6c2-b4d8-4a6e-b422-f2b27ffa81de' | System           | 03 Nov 2020 17:10:27 |
| User entered '03 Nov 2020 12:10'   | System           | 03 Nov 2020 17:10:27 |

**US3712308**

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

**Form: Headache\_Day(12)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '03 Nov 2020 12:00' | System           | 01 Nov 2020 18:32:15 |

**US3712308**

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

**Form: Headache\_Day(12)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '04 Nov 2020 11:59' | System           | 01 Nov 2020 18:32:15 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 02 Nov 2020 17:15:24 |
| User entered 'Day 13' | System           | 02 Nov 2020 17:15:24 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

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

**Form: Headache\_Day(13)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

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

**Form: Headache\_Day(13)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '04 Nov 2020 12:00' | System           | 02 Nov 2020 17:15:24 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(13)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '05 Nov 2020 11:59' | System           | 02 Nov 2020 17:15:24 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(14)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 03 Nov 2020 17:10:27 |
| User entered 'Day 14' | System           | 03 Nov 2020 17:10:27 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(14)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

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

**Form: Headache\_Day(14)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

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

**Form: Headache\_Day(14)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '05 Nov 2020 12:00' | System           | 03 Nov 2020 17:10:27 |

US3712308

Folder: Diary Dose 1 (1)

Form: Headache\_Day(14)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '06 Nov 2020 11:59' | System           | 03 Nov 2020 17:10:27 |

US3712308

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 28 Oct 2020 18:58:50 |
| User entered 'Day 8' | System           | 28 Oct 2020 18:58:50 |

US3712308

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-30T15:05:47', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '004a3d42-0b5a-4f51-846c-a32189655e1a' | System           | 30 Oct 2020 19:05:52 |
| User entered 'Some interference with activity (2)'   | System           | 30 Oct 2020 19:05:52 |

**US3712308**

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

**Form: Fatigue\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-30T15:05:49', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '004a3d42-0b5a-4f51-846c-a32189655e1a' | System           | 30 Oct 2020 19:05:52 |
| User entered '30 Oct 2020 15:05'   | System           | 30 Oct 2020 19:05:52 |

**US3712308**

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

**Form: Fatigue\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Oct 2020 12:00' | System           | 28 Oct 2020 18:58:50 |

**US3712308**

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

**Form: Fatigue\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '31 Oct 2020 11:59' | System           | 28 Oct 2020 18:58:50 |

**US3712308**

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

**Form: Fatigue\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 29 Oct 2020 17:12:45 |
| User entered 'Day 9' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-31T14:21:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '5bb182a4-484d-4c23-a43d-ed6c0f45f989' | System           | 31 Oct 2020 18:21:08 |
| User entered 'No interference with activity (1)'   | System           | 31 Oct 2020 18:21:08 |

**US3712308**

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

**Form: Fatigue\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-31T14:21:03', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '5bb182a4-484d-4c23-a43d-ed6c0f45f989' | System           | 31 Oct 2020 18:21:08 |
| User entered '31 Oct 2020 14:21'   | System           | 31 Oct 2020 18:21:08 |

US3712308

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '31 Oct 2020 12:00' | System           | 29 Oct 2020 17:12:45 |

**US3712308**

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

**Form: Fatigue\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '01 Nov 2020 11:59' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 30 Oct 2020 19:05:52 |
| User entered 'Day 10' | System           | 30 Oct 2020 19:05:52 |

US3712308

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-01T13:32:18', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '62f076fc-4d5f-4f02-9a42-5a5cbeed7acf' | System           | 01 Nov 2020 18:32:23 |
| User entered 'None (0)'  | System           | 01 Nov 2020 18:32:23 |

**US3712308**

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

**Form: Fatigue\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-01T13:32:21', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '62f076fc-4d5f-4f02-9a42-5a5cbeed7acf' | System           | 01 Nov 2020 18:32:23 |
| User entered '01 Nov 2020 13:32'   | System           | 01 Nov 2020 18:32:23 |

**US3712308**

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

**Form: Fatigue\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '01 Nov 2020 12:00' | System           | 30 Oct 2020 19:05:52 |

**US3712308**

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

**Form: Fatigue\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '02 Nov 2020 11:59' | System           | 30 Oct 2020 19:05:52 |

US3712308

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 29 Oct 2020 17:12:45 |
| User entered 'Day 8' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-30T15:05:55', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '09cee98a-e21e-41ef-9da7-2b56814ae2b6' | System           | 30 Oct 2020 19:05:59 |
| User entered 'No interference with activity (1)'   | System           | 30 Oct 2020 19:05:59 |

**US3712308**

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

**Form: MuscleAche\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-30T15:05:57', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '09cee98a-e21e-41ef-9da7-2b56814ae2b6' | System           | 30 Oct 2020 19:05:59 |
| User entered '30 Oct 2020 15:05'   | System           | 30 Oct 2020 19:05:59 |

**US3712308**

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

**Form: MuscleAche\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Oct 2020 12:00' | System           | 29 Oct 2020 17:12:45 |

**US3712308**

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

**Form: MuscleAche\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '31 Oct 2020 11:59' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 29 Oct 2020 17:12:45 |
| User entered 'Day 9' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-31T14:21:07', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ca491e2d-296e-45c3-b4d2-0f269cd38130' | System           | 31 Oct 2020 18:21:13 |
| User entered 'Some interference with activity (2)'   | System           | 31 Oct 2020 18:21:13 |

**US3712308**

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

**Form: MuscleAche\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-31T14:21:09', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ca491e2d-296e-45c3-b4d2-0f269cd38130' | System           | 31 Oct 2020 18:21:13 |
| User entered '31 Oct 2020 14:21'   | System           | 31 Oct 2020 18:21:13 |

**US3712308**

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

**Form: MuscleAche\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '31 Oct 2020 12:00' | System           | 29 Oct 2020 17:12:45 |

**US3712308**

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

**Form: MuscleAche\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '01 Nov 2020 11:59' | System           | 29 Oct 2020 17:12:45 |

**US3712308**

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

**Form: MuscleAche\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 30 Oct 2020 19:05:59 |
| User entered 'Day 10' | System           | 30 Oct 2020 19:05:59 |

US3712308

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(10)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-01T13:32:25', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '573da0a7-74d3-4be6-aede-bac42c59a847' | System           | 01 Nov 2020 18:32:30 |
| User entered 'No interference with activity (1)'   | System           | 01 Nov 2020 18:32:30 |

**US3712308**

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

**Form: MuscleAche\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-01T13:32:27', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '573da0a7-74d3-4be6-aede-bac42c59a847' | System           | 01 Nov 2020 18:32:30 |
| User entered '01 Nov 2020 13:32'   | System           | 01 Nov 2020 18:32:30 |

**US3712308**

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

**Form: MuscleAche\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '01 Nov 2020 12:00' | System           | 30 Oct 2020 19:05:59 |

**US3712308**

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

**Form: MuscleAche\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '02 Nov 2020 11:59' | System           | 30 Oct 2020 19:05:59 |

US3712308

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 31 Oct 2020 18:21:13 |
| User entered 'Day 11' | System           | 31 Oct 2020 18:21:13 |

US3712308

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(11)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-02T12:15:27', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fe0f9485-556e-453d-ab9b-5384780069f7' | System           | 02 Nov 2020 17:15:41 |
| User entered 'None (0)'  | System           | 02 Nov 2020 17:15:41 |

**US3712308**

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

**Form: MuscleAche\_Day(11)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-02T12:15:29', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fe0f9485-556e-453d-ab9b-5384780069f7' | System           | 02 Nov 2020 17:15:41 |
| User entered '02 Nov 2020 12:15'   | System           | 02 Nov 2020 17:15:41 |

**US3712308**

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

**Form: MuscleAche\_Day(11)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '02 Nov 2020 12:00' | System           | 31 Oct 2020 18:21:13 |

**US3712308**

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

**Form: MuscleAche\_Day(11)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '03 Nov 2020 11:59' | System           | 31 Oct 2020 18:21:13 |

**US3712308**

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

**Form: JointsAche\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 29 Oct 2020 17:12:45 |
| User entered 'Day 8' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-30T15:06:05', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8445116f-4909-4d3e-96d9-cd803cf8360f' | System           | 30 Oct 2020 19:06:12 |
| User entered 'None (0)'  | System           | 30 Oct 2020 19:06:12 |

**US3712308**

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

**Form: JointsAche\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-30T15:06:07', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8445116f-4909-4d3e-96d9-cd803cf8360f' | System           | 30 Oct 2020 19:06:12 |
| User entered '30 Oct 2020 15:06'   | System           | 30 Oct 2020 19:06:12 |

**US3712308**

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

**Form: JointsAche\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Oct 2020 12:00' | System           | 29 Oct 2020 17:12:45 |

**US3712308**

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

**Form: JointsAche\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '31 Oct 2020 11:59' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 29 Oct 2020 17:12:45 |
| User entered 'Day 8' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the level of your **NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-30T15:06:17', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '295e1965-e97e-4ac5-a0e6-9e8ecee09060' | System           | 30 Oct 2020 19:06:23 |
| User entered 'None (0)'  | System           | 30 Oct 2020 19:06:23 |

**US3712308**

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

**Form: Nausea\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-30T15:06:20', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '295e1965-e97e-4ac5-a0e6-9e8ecee09060' | System           | 30 Oct 2020 19:06:23 |
| User entered '30 Oct 2020 15:06'   | System           | 30 Oct 2020 19:06:23 |

US3712308

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Oct 2020 12:00' | System           | 29 Oct 2020 17:12:45 |

**US3712308**

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

**Form: Nausea\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '31 Oct 2020 11:59' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 28 Oct 2020 18:58:50 |
| User entered 'Day 8' | System           | 28 Oct 2020 18:58:50 |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-30T15:06:25', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd0b153c0-b4c9-4b76-a1fc-c0838cec1b80' | System           | 30 Oct 2020 19:06:30 |
| User entered 'No (N)'  | System           | 30 Oct 2020 19:06:30 |

**US3712308**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-30T15:06:27', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd0b153c0-b4c9-4b76-a1fc-c0838cec1b80' | System           | 30 Oct 2020 19:06:30 |
| User entered '30 Oct 2020 15:06'   | System           | 30 Oct 2020 19:06:30 |

**US3712308**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Oct 2020 12:00' | System           | 28 Oct 2020 18:58:50 |

**US3712308**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '31 Oct 2020 11:59' | System           | 28 Oct 2020 18:58:50 |

**US3712308**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 29 Oct 2020 17:12:45 |
| User entered 'Day 9' | System           | 29 Oct 2020 17:12:45 |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-31T14:21:13', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '290c03d2-497c-4c4f-bcb5-8ea6927b4a42' | System           | 31 Oct 2020 18:21:18 |
| User entered 'No (N)'  | System           | 31 Oct 2020 18:21:18 |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:23:35

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-10-31T14:21:15', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '290c03d2-497c-4c4f-bcb5-8ea6927b4a42' | System           | 31 Oct 2020 18:21:18 |
| User entered '31 Oct 2020 14:21'   | System           | 31 Oct 2020 18:21:18 |

**US3712308**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '31 Oct 2020 12:00' | System           | 29 Oct 2020 17:12:45 |

**US3712308**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '01 Nov 2020 11:59' | System           | 29 Oct 2020 17:12:45 |

**US3712308**

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

**Form: Medical Attention\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 30 Oct 2020 19:05:41 |
| User entered 'Day 10' | System           | 30 Oct 2020 19:05:41 |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-01T13:32:30', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '04905f8e-325c-47d3-afa7-4bced51ac837' | System           | 01 Nov 2020 18:32:37 |
| User entered 'No (N)'  | System           | 01 Nov 2020 18:32:37 |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 12 Aug 2021 13:23:35

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-01T13:32:32', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '04905f8e-325c-47d3-afa7-4bced51ac837' | System           | 01 Nov 2020 18:32:37 |
| User entered '01 Nov 2020 13:32'   | System           | 01 Nov 2020 18:32:37 |

**US3712308**

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

**Form: Medical Attention\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '01 Nov 2020 12:00' | System           | 30 Oct 2020 19:05:41 |

**US3712308**

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

**Form: Medical Attention\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '02 Nov 2020 11:59' | System           | 30 Oct 2020 19:05:41 |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 31 Oct 2020 18:20:57 |
| User entered 'Day 11' | System           | 31 Oct 2020 18:20:57 |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-02T12:15:32', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8040e849-6fae-4951-9479-22c598769bdc' | System           | 02 Nov 2020 17:15:44 |
| User entered 'No (N)'  | System           | 02 Nov 2020 17:15:44 |

**US3712308**

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

**Form: Medical Attention\_Day(11)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-02T12:15:34', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8040e849-6fae-4951-9479-22c598769bdc' | System           | 02 Nov 2020 17:15:44 |
| User entered '02 Nov 2020 12:15'   | System           | 02 Nov 2020 17:15:44 |

**US3712308**

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

**Form: Medical Attention\_Day(11)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '02 Nov 2020 12:00' | System           | 31 Oct 2020 18:20:57 |

**US3712308**

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

**Form: Medical Attention\_Day(11)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '03 Nov 2020 11:59' | System           | 31 Oct 2020 18:20:57 |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 02 Nov 2020 17:15:24 |
| User entered 'Day 13' | System           | 02 Nov 2020 17:15:24 |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
|                   |                  |                      |

**US3712308**

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

**Form: Medical Attention\_Day(13)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

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

**Form: Medical Attention\_Day(13)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '04 Nov 2020 12:00' | System           | 02 Nov 2020 17:15:24 |

**US3712308**

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

**Form: Medical Attention\_Day(13)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '05 Nov 2020 11:59' | System           | 02 Nov 2020 17:15:24 |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 03 Nov 2020 17:10:27 |
| User entered 'Day 14' | System           | 03 Nov 2020 17:10:27 |

US3712308

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
|                   |                  |                      |

**US3712308**

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

**Form: Medical Attention\_Day(14)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

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

**Form: Medical Attention\_Day(14)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '05 Nov 2020 12:00' | System           | 03 Nov 2020 17:10:27 |

**US3712308**

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

**Form: Medical Attention\_Day(14)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '06 Nov 2020 11:59' | System           | 03 Nov 2020 17:10:27 |

**US3712308**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 10 Nov 2020 15:32:05 |

**US3712308**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '30 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 10 Nov 2020 15:32:05 |

**US3712308**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 10 Nov 2020 15:32:05 |

**US3712308**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 10 Nov 2020 15:32:05 |

US3712308

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 10 Nov 2020 15:32:08 |

**US3712308**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered 'I'  | System           | 10 Nov 2020 15:32:08 |

**US3712308**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:53:06 |

**US3712308**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '06 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:53:06 |

**US3712308**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded.                  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:53:06 |

**US3712308**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:53:06 |

US3712308

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 08:35:14 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:00 |

**US3712308**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:35:14 |
| User entered 'I'  | System           | 23 Nov 2020 15:10:00 |

**US3712308**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:53:15 |

**US3712308**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '13 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:53:15 |

**US3712308**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.                  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:53:15 |

**US3712308**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:53:15 |

US3712308

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:04 |

**US3712308**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| User entered 'I'  | System           | 23 Nov 2020 15:10:04 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:13 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '23 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:13 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:35

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded.      | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:13 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered 'VISIT2' | System           | 23 Nov 2020 15:10:13 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '23 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '07:25'      | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered '23 Nov 2020 07:25' | System           | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '36.9' C     | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '78'         | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered 'bpm' | System           | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '20'         | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered 'breaths/min' | System           | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '125'        | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered 'mmHg' | System           | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '91'         | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered 'mmHg' | System           | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '23 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '10:06'      | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered '23 Nov 2020 10:06' | System           | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '36.9' C     | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '70'         | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered 'bpm' | System           | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '16'         | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered 'breaths/min' | System           | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '140'        | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered 'mmHg' | System           | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '92'         | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:59 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered 'mmHg' | System           | 03 Dec 2020 20:54:59 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:35

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:17 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:35

Date of examination (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:17 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Was the pregnancy test performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:28 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

Date of test (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '23 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:28 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

[Test performed](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded.    | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Urine (URINE)' | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:28 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Result](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded.          | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Negative (NEGATIVE)' | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:28 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

[Was FSH sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:28 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Collection date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:28 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Collection time](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 23 Nov 2020 15:10:28 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered empty. | System           | 23 Nov 2020 15:10:28 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[Was study treatment given?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:34:50 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 23 Nov 2020 15:10:47 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:23:35**

[If No, reason not given](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:34:50 |
| User entered empty.       | (b) (4), (b) (6)            | 23 Nov 2020 15:10:47 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

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)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:34:50 |
| User entered empty.       | (b) (4), (b) (6)            | 23 Nov 2020 15:10:47 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:34:50 |
| User entered '23 Nov 2020' | (b) (4), (b) (6)            | 23 Nov 2020 15:10:47 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:34:50 |
| User entered '09:31'      | (b) (4), (b) (6)            | 23 Nov 2020 15:10:47 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| User entered '23 Nov 2020 09:31' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[Which arm was used to give treatment?](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.          | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| DataPoint Verified.                | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 20:34:50 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4), (b) (6)            | 23 Nov 2020 15:10:47 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

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

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Feb 2021 20:34:50 |
| User entered 'ONCE' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| User entered 'INTRAMUSCULAR' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:35

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:53:58 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:35

Collection date (dd MMM yyyy)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21Dec2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6) | 25 Jan 2021 07:19:09 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21Dec2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'UPDATED' (Site from DM). | (b) (4), (b) (6)            | 22 Jan 2021 17:05:48 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 21Dec2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).             | (b) (4), (b) (6)            | 06 Jan 2021 17:08:18 |
| User entered '23 Nov 2020'   | (b) (4), (b) (6)            | 03 Dec 2020 20:53:58 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:35

Collection time (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '07:48'      | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:53:58 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered '23 Nov 2020 07:48' | System           | 03 Dec 2020 20:53:58 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:23:35

Collection date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '23 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:07 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | (b) (4), (b) (6) | 03 Dec 2020 20:54:07 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:23:35

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:07 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '07:53'      | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:07 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| User entered '23 Nov 2020 07:53' | System           | 03 Dec 2020 20:54:07 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Lab Test](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | (b) (4), (b) (6) | 03 Dec 2020 20:54:07 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:23:35

[Was the sample collected?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.                                 | William Smith (b) (4)       | 26 Mar 2021 23:53:27 |
| Signature has been broken.                                | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 21:36:08 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6)            | 12 Mar 2021 21:36:08 |
| User signature succeeded.                                 | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'                                    | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:07 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Collection time \(00:00 - 23:59\)](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.                              | William Smith (b) (4)       | 26 Mar 2021 23:53:27 |
| Signature has been broken.                             | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 21:36:08 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)            | 12 Mar 2021 21:36:08 |
| User signature succeeded.                              | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '07:53'                                   | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:07 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:23:35**

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

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| User entered empty.              | System           | 12 Mar 2021 21:36:08 |
| User entered '23 Nov 2020 07:53' | System           | 03 Dec 2020 20:54:07 |

US3712308

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 03 Dec 2020 20:54:09 |

**US3712308**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| User entered '1'  | System           | 03 Dec 2020 20:54:09 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:14:27', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ab030088-5b67-4939-92a2-e473cf94c66c' | System           | 23 Nov 2020 15:16:06 |
| User entered 'Yes (Y)'   | System           | 23 Nov 2020 15:16:06 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:15:56', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ab030088-5b67-4939-92a2-e473cf94c66c' | System           | 23 Nov 2020 15:16:06 |
| User entered '98.5'  | System           | 23 Nov 2020 15:16:06 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:15:59', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ab030088-5b67-4939-92a2-e473cf94c66c' | System           | 23 Nov 2020 15:16:06 |
| User entered 'No (N)'  | System           | 23 Nov 2020 15:16:06 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:02', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ab030088-5b67-4939-92a2-e473cf94c66c' | System           | 23 Nov 2020 15:16:06 |
| User entered '23 Nov 2020 10:16'   | System           | 23 Nov 2020 15:16:06 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Nov 2020 09:51' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Nov 2020 12:21' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.                                | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 1, after vaccination (at home)' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Nov 2020 13:16' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '24 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 2' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:33:08', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'a9be4ab4-5011-4e28-a881-11d702875e65' | System           | 25 Nov 2020 04:33:22 |
| User entered 'Yes (Y)'   | System           | 25 Nov 2020 04:33:22 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:33:16', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'a9be4ab4-5011-4e28-a881-11d702875e65' | System           | 25 Nov 2020 04:33:22 |
| User entered '97.6'  | System           | 25 Nov 2020 04:33:22 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:33:18', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'a9be4ab4-5011-4e28-a881-11d702875e65' | System           | 25 Nov 2020 04:33:22 |
| User entered 'No (N)'  | System           | 25 Nov 2020 04:33:22 |

**US3712308**

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

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:33:20', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'a9be4ab4-5011-4e28-a881-11d702875e65' | System           | 25 Nov 2020 04:33:22 |
| User entered '24 Nov 2020 23:33'   | System           | 25 Nov 2020 04:33:22 |

**US3712308**

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

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '24 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '25 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 3' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

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

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

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '25 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '26 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 4' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:49', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '42662a13-1305-46f8-bf74-e3516a735391' | System           | 27 Nov 2020 04:34:57 |
| User entered 'No (N)'  | System           | 27 Nov 2020 04:34:57 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:53', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '42662a13-1305-46f8-bf74-e3516a735391' | System           | 27 Nov 2020 04:34:57 |
| User entered 'No (N)'  | System           | 27 Nov 2020 04:34:57 |

**US3712308**

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

**Form: Temperature\_Day(4)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:55', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '42662a13-1305-46f8-bf74-e3516a735391' | System           | 27 Nov 2020 04:34:57 |
| User entered '26 Nov 2020 23:34'   | System           | 27 Nov 2020 04:34:57 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '26 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '27 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 5' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

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

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '27 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '28 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 6' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:34:48', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '1817207a-9993-4299-a6a3-5289b6b1ed43' | System           | 28 Nov 2020 17:37:17 |
| User entered 'Yes (Y)'   | System           | 28 Nov 2020 17:37:17 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:09', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '1817207a-9993-4299-a6a3-5289b6b1ed43' | System           | 28 Nov 2020 17:37:17 |
| User entered '97.8'  | System           | 28 Nov 2020 17:37:17 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:12', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '1817207a-9993-4299-a6a3-5289b6b1ed43' | System           | 28 Nov 2020 17:37:17 |
| User entered 'No (N)'  | System           | 28 Nov 2020 17:37:17 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:14', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '1817207a-9993-4299-a6a3-5289b6b1ed43' | System           | 28 Nov 2020 17:37:17 |
| User entered '28 Nov 2020 12:37'   | System           | 28 Nov 2020 17:37:17 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '28 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '29 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 7' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:33:02', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '35e1dd71-79da-401a-9076-35e5d072ec0b' | System           | 29 Nov 2020 22:33:19 |
| User entered 'Yes (Y)'   | System           | 29 Nov 2020 22:33:19 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:33:08', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '35e1dd71-79da-401a-9076-35e5d072ec0b' User entered '98.2' | System           | 29 Nov 2020 22:33:19 |
|  | System           | 29 Nov 2020 22:33:19 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:33:12', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '35e1dd71-79da-401a-9076-35e5d072ec0b' | System           | 29 Nov 2020 22:33:19 |
| User entered 'No (N)'  | System           | 29 Nov 2020 22:33:19 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:33:14', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '35e1dd71-79da-401a-9076-35e5d072ec0b' | System           | 29 Nov 2020 22:33:19 |
| User entered '29 Nov 2020 17:33'   | System           | 29 Nov 2020 22:33:19 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '29 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

TIMEPOINT

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:09', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3e2c060b-1ba6-4a81-8798-dede8b8065f8' | System           | 23 Nov 2020 15:16:22 |
| User entered 'Does not interfere with activity (2)'  | System           | 23 Nov 2020 15:16:22 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:12', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3e2c060b-1ba6-4a81-8798-dede8b8065f8' | System           | 23 Nov 2020 15:16:22 |
| User entered 'No (N)'  | System           | 23 Nov 2020 15:16:22 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:14', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3e2c060b-1ba6-4a81-8798-dede8b8065f8' | System           | 23 Nov 2020 15:16:22 |
| User entered 'No (N)'  | System           | 23 Nov 2020 15:16:22 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:17', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3e2c060b-1ba6-4a81-8798-dede8b8065f8' | System           | 23 Nov 2020 15:16:22 |
| User entered 'None (1)'  | System           | 23 Nov 2020 15:16:22 |

**US3712308**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:19', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3e2c060b-1ba6-4a81-8798-dede8b8065f8' | System           | 23 Nov 2020 15:16:22 |
| User entered '23 Nov 2020 10:16'   | System           | 23 Nov 2020 15:16:22 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Nov 2020 09:51' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Nov 2020 12:21' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.                                | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 1, after vaccination (at home)' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

Is there any REDNESS AT INJECTION SITE?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
|                   |                  |                      |

**US3712308**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Nov 2020 13:16' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '24 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 2' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:32:10', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '059379ee-57dc-4aca-b9d8-edc7fe9c29be' | System           | 25 Nov 2020 04:32:29 |
| User entered 'None (1)'  | System           | 25 Nov 2020 04:32:29 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:32:13', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '059379ee-57dc-4aca-b9d8-edc7fe9c29be' | System           | 25 Nov 2020 04:32:29 |
| User entered 'No (N)'  | System           | 25 Nov 2020 04:32:29 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:32:16', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '059379ee-57dc-4aca-b9d8-edc7fe9c29be' | System           | 25 Nov 2020 04:32:29 |
| User entered 'No (N)'  | System           | 25 Nov 2020 04:32:29 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:32:22', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '059379ee-57dc-4aca-b9d8-edc7fe9c29be' | System           | 25 Nov 2020 04:32:29 |
| User entered 'None (1)'  | System           | 25 Nov 2020 04:32:29 |

**US3712308**

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

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:32:25', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '059379ee-57dc-4aca-b9d8-edc7fe9c29be' | System           | 25 Nov 2020 04:32:29 |
| User entered '24 Nov 2020 23:32'   | System           | 25 Nov 2020 04:32:29 |

**US3712308**

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

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '24 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '25 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 3' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

Is there any REDNESS AT INJECTION SITE?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
|                   |                  |                      |

**US3712308**

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

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '25 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

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

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '26 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 4' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:33:55', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '01aeff72-ee44-401a-94ba-71effb76f013' | System           | 27 Nov 2020 04:34:19 |
| User entered 'None (1)'  | System           | 27 Nov 2020 04:34:19 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:33:58', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '01aeff72-ee44-401a-94ba-71effb76f013' | System           | 27 Nov 2020 04:34:19 |
| User entered 'No (N)'  | System           | 27 Nov 2020 04:34:19 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:01', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '01aeff72-ee44-401a-94ba-71effb76f013' | System           | 27 Nov 2020 04:34:19 |
| User entered 'No (N)'  | System           | 27 Nov 2020 04:34:19 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:11', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '01aeff72-ee44-401a-94ba-71effb76f013' | System           | 27 Nov 2020 04:34:19 |
| User entered 'Does not interfere with activity (2)'  | System           | 27 Nov 2020 04:34:19 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:14', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '01aeff72-ee44-401a-94ba-71effb76f013' | System           | 27 Nov 2020 04:34:19 |
| User entered '26 Nov 2020 23:34'   | System           | 27 Nov 2020 04:34:19 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '26 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '27 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 5' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-27T18:08:09', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f66c04df-cd60-430a-8fe9-c395163d6ad2' | System           | 27 Nov 2020 23:08:29 |
| User entered 'None (1)'  | System           | 27 Nov 2020 23:08:29 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:35

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-27T18:08:12', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f66c04df-cd60-430a-8fe9-c395163d6ad2' | System           | 27 Nov 2020 23:08:29 |
| User entered 'No (N)'  | System           | 27 Nov 2020 23:08:29 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-27T18:08:15', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f66c04df-cd60-430a-8fe9-c395163d6ad2' | System           | 27 Nov 2020 23:08:29 |
| User entered 'No (N)'  | System           | 27 Nov 2020 23:08:29 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-27T18:08:17', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f66c04df-cd60-430a-8fe9-c395163d6ad2' | System           | 27 Nov 2020 23:08:29 |
| User entered 'None (1)'  | System           | 27 Nov 2020 23:08:29 |

**US3712308**

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

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-27T18:08:25', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f66c04df-cd60-430a-8fe9-c395163d6ad2' | System           | 27 Nov 2020 23:08:29 |
| User entered '27 Nov 2020 18:08'   | System           | 27 Nov 2020 23:08:29 |

**US3712308**

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

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '27 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

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

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '28 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 6' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:17', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '9016cb6a-55ae-4df4-bc04-1a4e37470772' | System           | 28 Nov 2020 17:37:38 |
| User entered 'None (1)'  | System           | 28 Nov 2020 17:37:38 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:19', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '9016cb6a-55ae-4df4-bc04-1a4e37470772' | System           | 28 Nov 2020 17:37:38 |
| User entered 'No (N)'  | System           | 28 Nov 2020 17:37:38 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:22', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '9016cb6a-55ae-4df4-bc04-1a4e37470772' | System           | 28 Nov 2020 17:37:38 |
| User entered 'No (N)'  | System           | 28 Nov 2020 17:37:38 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:24', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '9016cb6a-55ae-4df4-bc04-1a4e37470772' | System           | 28 Nov 2020 17:37:38 |
| User entered 'None (1)'  | System           | 28 Nov 2020 17:37:38 |

**US3712308**

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

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:34', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '9016cb6a-55ae-4df4-bc04-1a4e37470772' | System           | 28 Nov 2020 17:37:38 |
| User entered '28 Nov 2020 12:37'   | System           | 28 Nov 2020 17:37:38 |

**US3712308**

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

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '28 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

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

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '29 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 7' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:32:46', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '567d2b89-17ab-446b-a2bf-af3c5f0f2e14' | System           | 29 Nov 2020 22:33:03 |
| User entered 'None (1)'  | System           | 29 Nov 2020 22:33:03 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:32:49', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '567d2b89-17ab-446b-a2bf-af3c5f0f2e14' | System           | 29 Nov 2020 22:33:03 |
| User entered 'No (N)'  | System           | 29 Nov 2020 22:33:03 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:32:51', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '567d2b89-17ab-446b-a2bf-af3c5f0f2e14' | System           | 29 Nov 2020 22:33:03 |
| User entered 'No (N)'  | System           | 29 Nov 2020 22:33:03 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:32:54', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '567d2b89-17ab-446b-a2bf-af3c5f0f2e14' | System           | 29 Nov 2020 22:33:03 |
| User entered 'None (1)'  | System           | 29 Nov 2020 22:33:03 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:32:57', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '567d2b89-17ab-446b-a2bf-af3c5f0f2e14' | System           | 29 Nov 2020 22:33:03 |
| User entered '29 Nov 2020 17:32'   | System           | 29 Nov 2020 22:33:03 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '29 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:25', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '6240de7c-2593-4dee-a1b0-310fbd366947' | System           | 23 Nov 2020 15:16:44 |
| User entered 'None (0)'  | System           | 23 Nov 2020 15:16:44 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:27', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '6240de7c-2593-4dee-a1b0-310fbd366947' | System           | 23 Nov 2020 15:16:44 |
| User entered 'None (0)'  | System           | 23 Nov 2020 15:16:44 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:29', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '6240de7c-2593-4dee-a1b0-310fbd366947' | System           | 23 Nov 2020 15:16:44 |
| User entered 'None (0)'  | System           | 23 Nov 2020 15:16:44 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:31', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '6240de7c-2593-4dee-a1b0-310fbd366947' | System           | 23 Nov 2020 15:16:44 |
| User entered 'None (0)'  | System           | 23 Nov 2020 15:16:44 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:32', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '6240de7c-2593-4dee-a1b0-310fbd366947' | System           | 23 Nov 2020 15:16:44 |
| User entered 'None (0)'  | System           | 23 Nov 2020 15:16:44 |

**US3712308**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:23:35**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:34', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '6240de7c-2593-4dee-a1b0-310fbd366947' | System           | 23 Nov 2020 15:16:44 |
| User entered 'None (0)'  | System           | 23 Nov 2020 15:16:44 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:37', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '6240de7c-2593-4dee-a1b0-310fbd366947' | System           | 23 Nov 2020 15:16:44 |
| User entered 'No (N)'  | System           | 23 Nov 2020 15:16:44 |

**US3712308**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-23T10:16:39', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '6240de7c-2593-4dee-a1b0-310fbd366947' | System           | 23 Nov 2020 15:16:44 |
| User entered '23 Nov 2020 10:16'   | System           | 23 Nov 2020 15:16:44 |

**US3712308**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Nov 2020 09:51' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Nov 2020 12:21' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.                                | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 1, after vaccination (at home)' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:23:35**

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
|                   |                  |                      |

**US3712308**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '23 Nov 2020 13:16' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '24 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 2' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:32:30', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ef52c0f9-335f-48b3-bee6-41fc1fc0ce4a' | System           | 25 Nov 2020 04:32:59 |
| User entered 'No interference with activity (1)'   | System           | 25 Nov 2020 04:32:59 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:32:32', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ef52c0f9-335f-48b3-bee6-41fc1fc0ce4a' | System           | 25 Nov 2020 04:32:59 |
| User entered 'None (0)'  | System           | 25 Nov 2020 04:32:59 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:32:44', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ef52c0f9-335f-48b3-bee6-41fc1fc0ce4a' | System           | 25 Nov 2020 04:32:59 |
| User entered 'None (0)'  | System           | 25 Nov 2020 04:32:59 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:32:47', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ef52c0f9-335f-48b3-bee6-41fc1fc0ce4a' | System           | 25 Nov 2020 04:32:59 |
| User entered 'None (0)'  | System           | 25 Nov 2020 04:32:59 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:32:49', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ef52c0f9-335f-48b3-bee6-41fc1fc0ce4a' | System           | 25 Nov 2020 04:32:59 |
| User entered 'None (0)'  | System           | 25 Nov 2020 04:32:59 |

**US3712308**

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

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:32:51', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ef52c0f9-335f-48b3-bee6-41fc1fc0ce4a' | System           | 25 Nov 2020 04:32:59 |
| User entered 'None (0)'  | System           | 25 Nov 2020 04:32:59 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:32:54', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ef52c0f9-335f-48b3-bee6-41fc1fc0ce4a' | System           | 25 Nov 2020 04:32:59 |
| User entered 'No (N)'  | System           | 25 Nov 2020 04:32:59 |

**US3712308**

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

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-24T23:32:57', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ef52c0f9-335f-48b3-bee6-41fc1fc0ce4a' | System           | 25 Nov 2020 04:32:59 |
| User entered '24 Nov 2020 23:32'   | System           | 25 Nov 2020 04:32:59 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '24 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '25 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 3' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:23:35**

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:23:35**

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
|                   |                  |                      |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '25 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '26 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 4' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:19', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4bd3685c-b069-4819-8f99-3b660a8d2f51' | System           | 27 Nov 2020 04:34:46 |
| User entered 'No interference with activity (1)'   | System           | 27 Nov 2020 04:34:46 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:24', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4bd3685c-b069-4819-8f99-3b660a8d2f51' | System           | 27 Nov 2020 04:34:46 |
| User entered 'Some interference with activity (2)'   | System           | 27 Nov 2020 04:34:46 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:26', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4bd3685c-b069-4819-8f99-3b660a8d2f51' | System           | 27 Nov 2020 04:34:46 |
| User entered 'None (0)'  | System           | 27 Nov 2020 04:34:46 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:29', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4bd3685c-b069-4819-8f99-3b660a8d2f51' | System           | 27 Nov 2020 04:34:46 |
| User entered 'None (0)'  | System           | 27 Nov 2020 04:34:46 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:34', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4bd3685c-b069-4819-8f99-3b660a8d2f51' | System           | 27 Nov 2020 04:34:46 |
| User entered 'None (0)'  | System           | 27 Nov 2020 04:34:46 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:37', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4bd3685c-b069-4819-8f99-3b660a8d2f51' | System           | 27 Nov 2020 04:34:46 |
| User entered 'None (0)'  | System           | 27 Nov 2020 04:34:46 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:40', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4bd3685c-b069-4819-8f99-3b660a8d2f51' | System           | 27 Nov 2020 04:34:46 |
| User entered 'No (N)'  | System           | 27 Nov 2020 04:34:46 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-26T23:34:43', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4bd3685c-b069-4819-8f99-3b660a8d2f51' | System           | 27 Nov 2020 04:34:46 |
| User entered '26 Nov 2020 23:34'   | System           | 27 Nov 2020 04:34:46 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '26 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '27 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 5' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-27T18:08:30', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '936e32fe-ff4d-42bd-a28f-500425af3fe8' | System           | 27 Nov 2020 23:08:53 |
| User entered 'No interference with activity (1)'   | System           | 27 Nov 2020 23:08:53 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-27T18:08:33', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '936e32fe-ff4d-42bd-a28f-500425af3fe8' | System           | 27 Nov 2020 23:08:53 |
| User entered 'None (0)'  | System           | 27 Nov 2020 23:08:53 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-27T18:08:35', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '936e32fe-ff4d-42bd-a28f-500425af3fe8' | System           | 27 Nov 2020 23:08:53 |
| User entered 'None (0)'  | System           | 27 Nov 2020 23:08:53 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-27T18:08:37', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '936e32fe-ff4d-42bd-a28f-500425af3fe8' | System           | 27 Nov 2020 23:08:53 |
| User entered 'None (0)'  | System           | 27 Nov 2020 23:08:53 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-27T18:08:39', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '936e32fe-ff4d-42bd-a28f-500425af3fe8' | System           | 27 Nov 2020 23:08:53 |
| User entered 'None (0)'  | System           | 27 Nov 2020 23:08:53 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-27T18:08:41', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '936e32fe-ff4d-42bd-a28f-500425af3fe8' | System           | 27 Nov 2020 23:08:53 |
| User entered 'None (0)'  | System           | 27 Nov 2020 23:08:53 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-27T18:08:45', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '936e32fe-ff4d-42bd-a28f-500425af3fe8' | System           | 27 Nov 2020 23:08:53 |
| User entered 'No (N)'  | System           | 27 Nov 2020 23:08:53 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-27T18:08:48', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '936e32fe-ff4d-42bd-a28f-500425af3fe8' | System           | 27 Nov 2020 23:08:53 |
| User entered '27 Nov 2020 18:08'   | System           | 27 Nov 2020 23:08:53 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '27 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '28 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 6' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:23:35**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:38', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e5bd5d53-6874-4ead-be10-2b85a91bd32c' | System           | 28 Nov 2020 17:38:01 |
| User entered 'None (0)'  | System           | 28 Nov 2020 17:38:01 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:40', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e5bd5d53-6874-4ead-be10-2b85a91bd32c' | System           | 28 Nov 2020 17:38:01 |
| User entered 'None (0)'  | System           | 28 Nov 2020 17:38:01 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:43', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e5bd5d53-6874-4ead-be10-2b85a91bd32c' | System           | 28 Nov 2020 17:38:01 |
| User entered 'No interference with activity (1)'   | System           | 28 Nov 2020 17:38:01 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:46', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e5bd5d53-6874-4ead-be10-2b85a91bd32c' | System           | 28 Nov 2020 17:38:01 |
| User entered 'No interference with activity (1)'   | System           | 28 Nov 2020 17:38:01 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:48', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e5bd5d53-6874-4ead-be10-2b85a91bd32c' User entered 'None (0)' | System           | 28 Nov 2020 17:38:01 |
|  | System           | 28 Nov 2020 17:38:01 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:50', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e5bd5d53-6874-4ead-be10-2b85a91bd32c' | System           | 28 Nov 2020 17:38:01 |
| User entered 'None (0)'  | System           | 28 Nov 2020 17:38:01 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:53', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e5bd5d53-6874-4ead-be10-2b85a91bd32c' | System           | 28 Nov 2020 17:38:01 |
| User entered 'No (N)'  | System           | 28 Nov 2020 17:38:01 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-28T12:37:55', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'e5bd5d53-6874-4ead-be10-2b85a91bd32c' | System           | 28 Nov 2020 17:38:01 |
| User entered '28 Nov 2020 12:37'   | System           | 28 Nov 2020 17:38:01 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '28 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '29 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 23 Nov 2020 15:10:47 |
| User entered 'Day 7' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:31:49', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4ccf78d7-0eaa-4dda-9894-f4ac1a7be843' | System           | 29 Nov 2020 22:32:09 |
| User entered 'None (0)'  | System           | 29 Nov 2020 22:32:09 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:31:52', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4ccf78d7-0eaa-4dda-9894-f4ac1a7be843' | System           | 29 Nov 2020 22:32:09 |
| User entered 'None (0)'  | System           | 29 Nov 2020 22:32:09 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:31:54', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4ccf78d7-0eaa-4dda-9894-f4ac1a7be843' | System           | 29 Nov 2020 22:32:09 |
| User entered 'No interference with activity (1)'   | System           | 29 Nov 2020 22:32:09 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:31:56', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4ccf78d7-0eaa-4dda-9894-f4ac1a7be843' | System           | 29 Nov 2020 22:32:09 |
| User entered 'None (0)'  | System           | 29 Nov 2020 22:32:09 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:31:59', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4ccf78d7-0eaa-4dda-9894-f4ac1a7be843' | System           | 29 Nov 2020 22:32:09 |
| User entered 'None (0)'  | System           | 29 Nov 2020 22:32:09 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:23:35**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:32:01', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4ccf78d7-0eaa-4dda-9894-f4ac1a7be843' | System           | 29 Nov 2020 22:32:09 |
| User entered 'None (0)'  | System           | 29 Nov 2020 22:32:09 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:32:03', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4ccf78d7-0eaa-4dda-9894-f4ac1a7be843' | System           | 29 Nov 2020 22:32:09 |
| User entered 'No (N)'  | System           | 29 Nov 2020 22:32:09 |

US3712308

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:23:35

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-29T17:32:06', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4ccf78d7-0eaa-4dda-9894-f4ac1a7be843' | System           | 29 Nov 2020 22:32:09 |
| User entered '29 Nov 2020 17:32'   | System           | 29 Nov 2020 22:32:09 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '29 Nov 2020 12:00' | System           | 23 Nov 2020 15:10:47 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Nov 2020 11:59' | System           | 23 Nov 2020 15:10:47 |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 28 Nov 2020 17:38:01 |
| User entered 'Day 8' | System           | 28 Nov 2020 17:38:01 |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-30T16:17:17', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ec2d00e0-3240-4acf-8fd5-6a2596e5948f' | System           | 30 Nov 2020 21:17:34 |
| User entered 'No interference with activity (1)'   | System           | 30 Nov 2020 21:17:34 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-30T16:17:19', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ec2d00e0-3240-4acf-8fd5-6a2596e5948f' User entered '30 Nov 2020 16:17' | System           | 30 Nov 2020 21:17:34 |
|   | System           | 30 Nov 2020 21:17:34 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Nov 2020 12:00' | System           | 28 Nov 2020 17:38:01 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '01 Dec 2020 11:59' | System           | 28 Nov 2020 17:38:01 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 29 Nov 2020 22:32:09 |
| User entered 'Day 9' | System           | 29 Nov 2020 22:32:09 |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(9)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-12-02T00:31:35', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fd564eeb-eee6-46dc-b0fd-dd525f2457e1' | System           | 02 Dec 2020 05:31:40 |
| User entered 'No interference with activity (1)'   | System           | 02 Dec 2020 05:31:40 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-12-02T00:31:37', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'fd564eeb-eee6-46dc-b0fd-dd525f2457e1' | System           | 02 Dec 2020 05:31:40 |
| User entered '02 Dec 2020 00:31'   | System           | 02 Dec 2020 05:31:40 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '01 Dec 2020 12:00' | System           | 29 Nov 2020 22:32:09 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '02 Dec 2020 11:59' | System           | 29 Nov 2020 22:32:09 |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 30 Nov 2020 21:17:34 |
| User entered 'Day 10' | System           | 30 Nov 2020 21:17:34 |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(10)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-12-02T20:09:23', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '1b476b07-e985-4687-b894-5b58fac89ead' | System           | 03 Dec 2020 01:09:28 |
| User entered 'No interference with activity (1)'   | System           | 03 Dec 2020 01:09:28 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-12-02T20:09:24', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '1b476b07-e985-4687-b894-5b58fac89ead' | System           | 03 Dec 2020 01:09:28 |
| User entered '02 Dec 2020 20:09'   | System           | 03 Dec 2020 01:09:28 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '02 Dec 2020 12:00' | System           | 30 Nov 2020 21:17:34 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '03 Dec 2020 11:59' | System           | 30 Nov 2020 21:17:34 |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 02 Dec 2020 05:31:40 |
| User entered 'Day 11' | System           | 02 Dec 2020 05:31:40 |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(11)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '03 Dec 2020 12:00' | System           | 02 Dec 2020 05:31:40 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(11)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '04 Dec 2020 11:59' | System           | 02 Dec 2020 05:31:40 |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 03 Dec 2020 01:09:28 |
| User entered 'Day 12' | System           | 03 Dec 2020 01:09:28 |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 12 Aug 2021 13:23:35

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 12 Aug 2021 13:23:35

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '04 Dec 2020 12:00' | System           | 03 Dec 2020 01:09:28 |

US3712308

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(12)

Generated On: 12 Aug 2021 13:23:35

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '05 Dec 2020 11:59' | System           | 03 Dec 2020 01:09:28 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 28 Nov 2020 17:38:01 |
| User entered 'Day 8' | System           | 28 Nov 2020 17:38:01 |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-30T16:17:25', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'da9b3997-00d0-4c43-8956-c3623828485d' | System           | 30 Nov 2020 21:17:54 |
| User entered 'No (N)'  | System           | 30 Nov 2020 21:17:54 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-11-30T16:17:28', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'da9b3997-00d0-4c43-8956-c3623828485d' | System           | 30 Nov 2020 21:17:54 |
| User entered '30 Nov 2020 16:17'   | System           | 30 Nov 2020 21:17:54 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '30 Nov 2020 12:00' | System           | 28 Nov 2020 17:38:01 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '01 Dec 2020 11:59' | System           | 28 Nov 2020 17:38:01 |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.   | System           | 29 Nov 2020 22:32:09 |
| User entered 'Day 9' | System           | 29 Nov 2020 22:32:09 |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-12-02T00:31:41', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'c5b81b2b-9ceb-4356-b590-05c31a9b18e5' | System           | 02 Dec 2020 05:31:46 |
| User entered 'No (N)'  | System           | 02 Dec 2020 05:31:46 |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 12 Aug 2021 13:23:35

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-12-02T00:31:44', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'c5b81b2b-9ceb-4356-b590-05c31a9b18e5' | System           | 02 Dec 2020 05:31:46 |
| User entered '02 Dec 2020 00:31'   | System           | 02 Dec 2020 05:31:46 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '01 Dec 2020 12:00' | System           | 29 Nov 2020 22:32:09 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '02 Dec 2020 11:59' | System           | 29 Nov 2020 22:32:09 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 30 Nov 2020 21:17:34 |
| User entered 'Day 10' | System           | 30 Nov 2020 21:17:34 |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-12-02T20:09:33', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '10850cbe-9b32-44fb-9b21-3927b0e455c6' | System           | 03 Dec 2020 01:13:28 |
| User entered 'No (N)'  | System           | 03 Dec 2020 01:13:28 |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 12 Aug 2021 13:23:35

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-12-02T20:13:22', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '10850cbe-9b32-44fb-9b21-3927b0e455c6' | System           | 03 Dec 2020 01:13:28 |
| User entered '02 Dec 2020 20:13'   | System           | 03 Dec 2020 01:13:28 |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 12 Aug 2021 13:23:35

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '02 Dec 2020 12:00' | System           | 30 Nov 2020 21:17:34 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '03 Dec 2020 11:59' | System           | 30 Nov 2020 21:17:34 |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 02 Dec 2020 05:31:40 |
| User entered 'Day 11' | System           | 02 Dec 2020 05:31:40 |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(11)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
|                   |                  |                      |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '03 Dec 2020 12:00' | System           | 02 Dec 2020 05:31:40 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(11)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '04 Dec 2020 11:59' | System           | 02 Dec 2020 05:31:40 |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 12 Aug 2021 13:23:35

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| Data entry locked.    | System           | 03 Dec 2020 01:09:28 |
| User entered 'Day 12' | System           | 03 Dec 2020 01:09:28 |

US3712308

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(12)

Generated On: 12 Aug 2021 13:23:35

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 00:02:36 |
|                   |                  |                      |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
|                   |                  |                      |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '04 Dec 2020 12:00' | System           | 03 Dec 2020 01:09:28 |

**US3712308**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(12)**

**Generated On: 12 Aug 2021 13:23:35**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 05 Mar 2021 00:02:36 |
| User entered '05 Dec 2020 11:59' | System           | 03 Dec 2020 01:09:28 |

**US3712308**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 17:07:49 |

**US3712308**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '30 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 17:07:49 |

**US3712308**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.                  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 17:07:49 |

**US3712308**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 17:07:49 |

US3712308

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:55:49 |

**US3712308**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| User entered '1'  | System           | 07 Jan 2021 20:55:49 |

**US3712308**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 17:09:24 |

**US3712308**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '07 Dec 2020' | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 17:09:24 |

**US3712308**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.                  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 17:09:24 |

**US3712308**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 17:09:24 |

US3712308

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:55:55 |

**US3712308**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| User entered 'I'  | System           | 07 Jan 2021 20:55:55 |

**US3712308**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 17:09:43 |

**US3712308**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered '14 Dec 2020' | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 17:09:43 |

**US3712308**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.                  | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 17:09:43 |

**US3712308**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 17:09:43 |

US3712308

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:55:59 |

**US3712308**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| User entered 'I'  | System           | 07 Jan 2021 20:55:59 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:08 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '21 Dec 2020' | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:08 |

US3712308

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:35

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded.      | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:08 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered 'VISIT3' | System           | 07 Jan 2021 20:56:08 |

US3712308

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:16 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

**Date of assessment** (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:16 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:16 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered empty. | System           | 07 Jan 2021 20:56:16 |

US3712308

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:16 |

US3712308

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Route of measurement](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:16 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:16 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:16 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered empty. | System           | 07 Jan 2021 20:56:16 |

US3712308

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:16 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Respiratory Rate units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered empty. | System           | 07 Jan 2021 20:56:16 |

US3712308

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:16 |

US3712308

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered empty. | System           | 07 Jan 2021 20:56:16 |

US3712308

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

Diastolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:16 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered empty. | System           | 07 Jan 2021 20:56:16 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
|                   |                  |                      |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:23:35**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:19 |

US3712308

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:35

Date of examination (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:19 |

US3712308

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:35

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:24 |

US3712308

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:35

Collection date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded.  | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '21 Dec 2020' | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:24 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:23:35**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered '08:48'      | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:24 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:23:35**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered '21 Dec 2020 08:48' | System           | 07 Jan 2021 20:56:24 |

US3712308

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 15:34:19 |
| User signature succeeded. | William Smith (b) (4)       | 13 Feb 2021 20:45:32 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 07 Jan 2021 20:56:27 |

**US3712308**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 15:34:19 |
| User entered '1'  | System           | 07 Jan 2021 20:56:27 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 61' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2020-12-21T21:47:32', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4c4568f5-99cd-4516-968f-16f9341d893f' | System | 22 Dec 2020 02:47:45 |
| User entered 'No (N)'  | System | 22 Dec 2020 02:47:45 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2020-12-21T21:47:38', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4c4568f5-99cd-4516-968f-16f9341d893f' | System | 22 Dec 2020 02:47:45 |
| User entered 'No (N)'  | System | 22 Dec 2020 02:47:45 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-12-21T21:47:41', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4c4568f5-99cd-4516-968f-16f9341d893f' | System | 22 Dec 2020 02:47:45 |
| User entered '21 Dec 2020 21:47:41'  | System | 22 Dec 2020 02:47:45 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '20 Dec 2020 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '24 Dec 2020 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 68' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2020-12-27T23:20:23', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '30637d5c-5726-4726-a54b-5df6739e58fa' | System | 28 Dec 2020 05:21:01 |
| User entered 'No (N)'  | System | 28 Dec 2020 05:21:01 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2020-12-27T23:20:54', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '30637d5c-5726-4726-a54b-5df6739e58fa' | System | 28 Dec 2020 05:21:01 |
| User entered 'No (N)'  | System | 28 Dec 2020 05:21:01 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2020-12-27T23:20:56', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '30637d5c-5726-4726-a54b-5df6739e58fa' | System | 28 Dec 2020 05:21:01 |
| User entered '27 Dec 2020 23:20:56'  | System | 28 Dec 2020 05:21:01 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '27 Dec 2020 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '31 Dec 2020 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 75' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-01-05T12:16:59', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '5da60821-3a79-484b-9110-f56d2615c76d' | System | 05 Jan 2021 17:17:25 |
| User entered 'No (N)'  | System | 05 Jan 2021 17:17:25 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-01-05T12:17:17', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '5da60821-3a79-484b-9110-f56d2615c76d' | System | 05 Jan 2021 17:17:25 |
| User entered 'No (N)'  | System | 05 Jan 2021 17:17:25 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-01-05T12:17:20', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '5da60821-3a79-484b-9110-f56d2615c76d' User entered '05 Jan 2021 12:17:20' | System | 05 Jan 2021 17:17:25 |
|  | System | 05 Jan 2021 17:17:25 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '03 Jan 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '07 Jan 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-01-11T09:51:35', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '7853e33d-930c-4407-b5d2-8544fb0f1ce8' | System | 11 Jan 2021 14:52:06 |
| User entered 'No (N)'  | System | 11 Jan 2021 14:52:06 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-01-11T09:51:50', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '7853e33d-930c-4407-b5d2-8544fb0f1ce8' | System | 11 Jan 2021 14:52:06 |
| User entered 'Yes (Y)'   | System | 11 Jan 2021 14:52:06 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-01-11T09:51:54', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '7853e33d-930c-4407-b5d2-8544fb0f1ce8' | System | 11 Jan 2021 14:52:06 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 11 Jan 2021 14:52:06 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-01-11T09:51:57', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '7853e33d-930c-4407-b5d2-8544fb0f1ce8' User entered '11 Jan 2021 09:51:57' | System | 11 Jan 2021 14:52:06 |
|  | System | 11 Jan 2021 14:52:06 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '10 Jan 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '14 Jan 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-01-19T03:48:40', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3868cb52-5b5c-4653-9732-1429bbe882b3' | System | 19 Jan 2021 08:48:54 |
| User entered 'No (N)'  | System | 19 Jan 2021 08:48:54 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-01-19T03:48:47', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3868cb52-5b5c-4653-9732-1429bbe882b3' | System | 19 Jan 2021 08:48:54 |
| User entered 'No (N)'  | System | 19 Jan 2021 08:48:54 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-01-19T03:48:50', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '3868cb52-5b5c-4653-9732-1429bbe882b3' | System | 19 Jan 2021 08:48:54 |
| User entered '19 Jan 2021 03:48:50'  | System | 19 Jan 2021 08:48:54 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '17 Jan 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '21 Jan 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-01-24T21:05:53', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'b48b785e-8ad5-491c-8086-ebccec2021a4' | System | 25 Jan 2021 02:06:28 |
| User entered 'No (N)'  | System | 25 Jan 2021 02:06:28 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-01-24T21:05:56', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'b48b785e-8ad5-491c-8086-ebccec2021a4' | System | 25 Jan 2021 02:06:28 |
| User entered 'No (N)'  | System | 25 Jan 2021 02:06:28 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-01-24T21:05:59', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'b48b785e-8ad5-491c-8086-ebccec2021a4' | System | 25 Jan 2021 02:06:28 |
| User entered '24 Jan 2021 21:05:59'  | System | 25 Jan 2021 02:06:28 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '24 Jan 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '28 Jan 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-01-31T11:54:27', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd9f542df-8c20-493b-8252-17b50ed6ec01' | System | 31 Jan 2021 16:54:35 |
| User entered 'No (N)'  | System | 31 Jan 2021 16:54:35 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-01-31T11:54:30', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd9f542df-8c20-493b-8252-17b50ed6ec01' | System | 31 Jan 2021 16:54:35 |
| User entered 'No (N)'  | System | 31 Jan 2021 16:54:35 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-01-31T11:54:33', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'd9f542df-8c20-493b-8252-17b50ed6ec01' | System | 31 Jan 2021 16:54:35 |
| User entered '31 Jan 2021 11:54:33'  | System | 31 Jan 2021 16:54:35 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '31 Jan 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '04 Feb 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-02-09T14:20:46', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '97a4a65d-7f74-4868-b339-3bbbdd526128' | System | 09 Feb 2021 19:20:57 |
| User entered 'No (N)'  | System | 09 Feb 2021 19:20:57 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-02-09T14:20:48', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '97a4a65d-7f74-4868-b339-3bbbdd526128' | System | 09 Feb 2021 19:20:57 |
| User entered 'No (N)'  | System | 09 Feb 2021 19:20:57 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-02-09T14:20:51', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '97a4a65d-7f74-4868-b339-3bbbdd526128' User entered '09 Feb 2021 14:20:51' | System | 09 Feb 2021 19:20:57 |
|  | System | 09 Feb 2021 19:20:57 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '07 Feb 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '11 Feb 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-02-14T11:58:22', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f9ff109f-70ed-4463-a063-04359175222a' | System | 14 Feb 2021 16:58:34 |
| User entered 'No (N)'  | System | 14 Feb 2021 16:58:34 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-02-14T11:58:24', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f9ff109f-70ed-4463-a063-04359175222a' | System | 14 Feb 2021 16:58:34 |
| User entered 'No (N)'  | System | 14 Feb 2021 16:58:34 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-02-14T11:58:26', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f9ff109f-70ed-4463-a063-04359175222a' User entered '14 Feb 2021 11:58:26' | System | 14 Feb 2021 16:58:34 |
|  | System | 14 Feb 2021 16:58:34 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '14 Feb 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '18 Feb 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-02-21T01:02:34', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4b8e0675-278a-4798-8e3d-caabb672583c' | System | 21 Feb 2021 06:02:57 |
| User entered 'No (N)'  | System | 21 Feb 2021 06:02:57 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-02-21T01:02:37', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4b8e0675-278a-4798-8e3d-caabb672583c' | System | 21 Feb 2021 06:02:57 |
| User entered 'No (N)'  | System | 21 Feb 2021 06:02:57 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-02-21T01:02:40', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '4b8e0675-278a-4798-8e3d-caabb672583c' | System | 21 Feb 2021 06:02:57 |
| User entered '21 Feb 2021 01:02:40'  | System | 21 Feb 2021 06:02:57 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '21 Feb 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '25 Feb 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-02-28T19:13:35-05:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f86198b5-5681-407f-ae34-0272e14fcf6c' | System | 01 Mar 2021 00:14:31 |
| User entered 'No (N)'  | System | 01 Mar 2021 00:14:31 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-02-28T19:13:39-05:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f86198b5-5681-407f-ae34-0272e14fcf6c' | System | 01 Mar 2021 00:14:31 |
| User entered 'No (N)'  | System | 01 Mar 2021 00:14:31 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-02-28T19:13:42-05:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f86198b5-5681-407f-ae34-0272e14fcf6c' | System | 01 Mar 2021 00:14:31 |
| User entered '28 Feb 2021 19:13:42'  | System | 01 Mar 2021 00:14:31 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '28 Feb 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '04 Mar 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-03-07T20:05:42-05:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f26d87d2-da3c-4cf9-87d3-2fe2fa86dbfa' | System | 08 Mar 2021 01:05:56 |
| User entered 'No (N)'  | System | 08 Mar 2021 01:05:56 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-03-07T20:05:45-05:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f26d87d2-da3c-4cf9-87d3-2fe2fa86dbfa' | System | 08 Mar 2021 01:05:56 |
| User entered 'No (N)'  | System | 08 Mar 2021 01:05:56 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-03-07T20:05:48-05:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'f26d87d2-da3c-4cf9-87d3-2fe2fa86dbfa' User entered '07 Mar 2021 20:05:48' | System | 08 Mar 2021 01:05:56 |
|  | System | 08 Mar 2021 01:05:56 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '07 Mar 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '11 Mar 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-03-14T15:51:19-04:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '535f77f3-80d9-4cbb-807f-81d5c3e9971c' | System | 14 Mar 2021 19:51:28 |
| User entered 'No (N)'  | System | 14 Mar 2021 19:51:28 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-03-14T15:51:21-04:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '535f77f3-80d9-4cbb-807f-81d5c3e9971c' | System | 14 Mar 2021 19:51:28 |
| User entered 'No (N)'  | System | 14 Mar 2021 19:51:28 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-03-14T15:51:26-04:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '535f77f3-80d9-4cbb-807f-81d5c3e9971c' | System | 14 Mar 2021 19:51:28 |
| User entered '14 Mar 2021 15:51:26'  | System | 14 Mar 2021 19:51:28 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '14 Mar 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '18 Mar 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-03-21T14:11:17-04:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'a74805b2-0bbe-4c55-84eb-9e3da528c367' | System | 21 Mar 2021 18:11:28 |
| User entered 'No (N)'  | System | 21 Mar 2021 18:11:28 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-03-21T14:11:20-04:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'a74805b2-0bbe-4c55-84eb-9e3da528c367' | System | 21 Mar 2021 18:11:28 |
| User entered 'No (N)'  | System | 21 Mar 2021 18:11:28 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-03-21T14:11:22-04:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'a74805b2-0bbe-4c55-84eb-9e3da528c367' | System | 21 Mar 2021 18:11:28 |
| User entered '21 Mar 2021 14:11:22'  | System | 21 Mar 2021 18:11:28 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '21 Mar 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '25 Mar 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-03-28T03:33:35-04:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'b56da3f7-fdd8-4b14-a918-d26cddaaef41' | System | 28 Mar 2021 07:33:45 |
| User entered 'No (N)'  | System | 28 Mar 2021 07:33:45 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-03-28T03:33:38-04:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'b56da3f7-fdd8-4b14-a918-d26cddaaef41' | System | 28 Mar 2021 07:33:45 |
| User entered 'No (N)'  | System | 28 Mar 2021 07:33:45 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-03-28T03:33:41-04:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'b56da3f7-fdd8-4b14-a918-d26cddaaef41' | System | 28 Mar 2021 07:33:45 |
| User entered '28 Mar 2021 03:33:41'  | System | 28 Mar 2021 07:33:45 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '28 Mar 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '01 Apr 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '04 Apr 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '08 Apr 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '11 Apr 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '15 Apr 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[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 (858cc67891c94319)', Time: '2021-04-18T00:23:38-04:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ecfacd27-6680-42a6-bdd5-d26b0af0e3a5' | System | 18 Apr 2021 04:23:48 |
| User entered 'No (N)'  | System | 18 Apr 2021 04:23:48 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

Have you been exposed to someone with 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 (858cc67891c94319)', Time: '2021-04-18T00:23:41-04:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ecfacd27-6680-42a6-bdd5-d26b0af0e3a5' | System | 18 Apr 2021 04:23:48 |
| User entered 'No (N)'  | System | 18 Apr 2021 04:23:48 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-04-18T00:23:44-04:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: 'ecfacd27-6680-42a6-bdd5-d26b0af0e3a5' | System | 18 Apr 2021 04:23:48 |
| User entered '18 Apr 2021 00:23:44'  | System | 18 Apr 2021 04:23:48 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '18 Apr 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '22 Apr 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '25 Apr 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '29 Apr 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '02 May 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '06 May 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '09 May 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '13 May 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '16 May 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '20 May 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '23 May 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '27 May 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '30 May 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '03 Jun 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '06 Jun 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '10 Jun 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '13 Jun 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '17 Jun 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '20 Jun 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '24 Jun 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '27 Jun 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '01 Jul 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '04 Jul 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '08 Jul 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '11 Jul 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '15 Jul 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '18 Jul 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '22 Jul 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '25 Jul 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '29 Jul 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '01 Aug 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '05 Aug 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '08 Aug 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '12 Aug 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '15 Aug 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '19 Aug 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '22 Aug 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '26 Aug 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '29 Aug 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '02 Sep 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '05 Sep 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '09 Sep 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '12 Sep 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '16 Sep 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '19 Sep 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '23 Sep 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '26 Sep 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '30 Sep 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '03 Oct 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '07 Oct 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '10 Oct 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '14 Oct 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '17 Oct 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '21 Oct 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '24 Oct 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '28 Oct 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '31 Oct 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '04 Nov 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '07 Nov 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '11 Nov 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '14 Nov 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '18 Nov 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '21 Nov 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '25 Nov 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '28 Nov 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '02 Dec 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '05 Dec 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '09 Dec 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '12 Dec 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '16 Dec 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '19 Dec 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '23 Dec 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '26 Dec 2021 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '30 Dec 2021 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '02 Jan 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '06 Jan 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '09 Jan 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '13 Jan 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '16 Jan 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '20 Jan 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '23 Jan 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '27 Jan 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '30 Jan 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '03 Feb 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '06 Feb 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '10 Feb 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '13 Feb 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '17 Feb 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '20 Feb 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '24 Feb 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '27 Feb 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '03 Mar 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '06 Mar 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '10 Mar 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '13 Mar 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '17 Mar 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '20 Mar 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '24 Mar 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '27 Mar 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '31 Mar 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '03 Apr 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '07 Apr 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '10 Apr 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '14 Apr 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '17 Apr 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '21 Apr 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '24 Apr 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '28 Apr 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '01 May 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '05 May 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '08 May 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '12 May 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '15 May 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '19 May 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '22 May 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '26 May 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '29 May 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '02 Jun 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '05 Jun 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '09 Jun 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '12 Jun 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '16 Jun 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '19 Jun 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '23 Jun 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '26 Jun 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '30 Jun 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 13:42:52 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '03 Jul 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '07 Jul 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 13:42:52 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '10 Jul 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**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 | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '14 Jul 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 13:42:52 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '17 Jul 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '21 Jul 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '24 Jul 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '28 Jul 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '31 Jul 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '04 Aug 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '07 Aug 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '11 Aug 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '14 Aug 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '18 Aug 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '21 Aug 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '25 Aug 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '28 Aug 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '01 Sep 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 13:42:52 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '04 Sep 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '08 Sep 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 13:42:52 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '11 Sep 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '15 Sep 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 13:42:52 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '18 Sep 2022 00:01' | System | 20 Nov 2020 13:42:52 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '22 Sep 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '25 Sep 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '29 Sep 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '02 Oct 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '06 Oct 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '09 Oct 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '13 Oct 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '16 Oct 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '20 Oct 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '23 Oct 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '27 Oct 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '30 Oct 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '03 Nov 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '06 Nov 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '10 Nov 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '13 Nov 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**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 | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '17 Nov 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '20 Nov 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '24 Nov 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 13:42:52 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '27 Nov 2022 00:01' | System | 20 Nov 2020 13:42:52 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '01 Dec 2022 23:59' | System | 20 Nov 2020 13:42:52 |

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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 13:42:52 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '04 Dec 2022 00:01' | System | 20 Nov 2020 13:42:52 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '08 Dec 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '11 Dec 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '15 Dec 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '18 Dec 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '22 Dec 2022 23:59' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '25 Dec 2022 00:01' | System | 20 Nov 2020 13:42:52 |

**US3712308**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:23:35**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 13:42:52 |
| Amendment Manager: User entered '29 Dec 2022 23:59' | System | 20 Nov 2020 13:42:52 |

US3712308

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:23:35

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) | 24 Apr 2021 23:30:46 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-02-27T20:55:18-05:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8e68f2ca-2e21-4d07-ab8f-6abdf536ed25' | System           | 28 Feb 2021 01:55:43 |
| User entered 'Yes (Y)'   | System           | 28 Feb 2021 01:55:43 |

US3712308

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:23:35

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?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 24 Apr 2021 23:30:46 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-02-27T20:55:25-05:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8e68f2ca-2e21-4d07-ab8f-6abdf536ed25' | System           | 28 Feb 2021 01:55:43 |
| User entered 'No (N)'  | System           | 28 Feb 2021 01:55:43 |

**US3712308**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Date & Time of Submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 24 Apr 2021 23:30:46 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (858cc67891c94319)', Time: '2021-02-27T20:55:30-05:00', User OID: 'PatientReportedOutcome (US3712308)', ODM File OID: '8e68f2ca-2e21-4d07-ab8f-6abdf536ed25' | System           | 28 Feb 2021 01:55:43 |
| User entered '27 Feb 2021 20:55:30'  | System           | 28 Feb 2021 01:55:43 |

US3712308

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:35

[Was Contact Attempted?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.   | William Smith (b) (4)       | 26 Mar 2021 23:53:27 |
| User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | (b) (4)                     | 15 Mar 2021 15:01:12 |
| User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | System                      | 15 Mar 2021 15:01:06 |
| Signature has been broken.  | (b) (4), (b) (6)            | 15 Mar 2021 15:01:06 |
| User entered 'No (N)' reason for change: Data Entry Error   | (b) (4), (b) (6)            | 15 Mar 2021 15:01:06 |
| User signature succeeded.   | William Smith (b) (4)       | 10 Mar 2021 02:39:58 |
| User entered 'Yes (Y)'  | (b) (4)<br>(b) (4), (b) (6) | 05 Feb 2021 17:27:12 |

US3712308

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:35

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.                              | William Smith (b) (4)       | 26 Mar 2021 23:53:27 |
| Signature has been broken.                             | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 15:01:06 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)            | 15 Mar 2021 15:01:06 |
| User signature succeeded.                              | William Smith (b) (4)       | 10 Mar 2021 02:39:58 |
| User entered '18 Jan 2021'                             | (b) (4)<br>(b) (4), (b) (6) | 05 Feb 2021 17:27:12 |

US3712308

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:35

[Please select one status for the follow-up contact](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.  | William Smith (b) (4)       | 26 Mar 2021 23:53:27 |
| User entered empty; reason for change Data Entry Error                                 | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 15:01:12 |
| Signature has been broken.   | (b) (4), (b) (6)            | 15 Mar 2021 15:01:06 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error | (b) (4), (b) (6)            | 15 Mar 2021 15:01:06 |
| User signature succeeded.  | William Smith (b) (4)       | 10 Mar 2021 02:39:58 |
| User entered 'Contact Made (CONTACT MADE)'   | (b) (4)<br>(b) (4), (b) (6) | 05 Feb 2021 17:27:12 |

US3712308

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:35

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 Apr 2021 15:34:18 |
| User signature succeeded.   | William Smith (b) (4)       | 26 Mar 2021 23:53:27 |
| Signature has been broken.  | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 15:01:06 |
| User entered 'subject in illness visit' reason for change: Data Entry Error | (b) (4), (b) (6)            | 15 Mar 2021 15:01:06 |
| User signature succeeded.   | William Smith (b) (4)       | 10 Mar 2021 02:39:58 |
| User entered empty.   | (b) (4)<br>(b) (4), (b) (6) | 05 Feb 2021 17:27:12 |

US3712308

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

[Is the participant continuing to the next visit?](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 03 Apr 2021 15:34:18 |
| User signature succeeded.  | William Smith (b) (4) | 10 Mar 2021 02:39:58 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 05 Feb 2021 17:27:28 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 05 Feb 2021 17:27:28 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | (b) (4), (b) (6)      | 05 Feb 2021 17:27:28 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 05 Feb 2021 17:27:25 |
| User entered empty.  | (b) (4), (b) (6)      | 05 Feb 2021 17:27:25 |

**US3712308**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 15:34:18 |
| User entered '1'    | System           | 05 Feb 2021 17:27:28 |
| User entered empty. | System           | 05 Feb 2021 17:27:25 |

US3712308

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:35

[Was Contact Attempted?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 14 Apr 2021 06:18:26 |
| User signature succeeded.   | William Smith (b) (4) | 05 Apr 2021 01:00:38 |
| User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | (b) (4)               | 15 Mar 2021 15:01:31 |
| User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System). | System                | 15 Mar 2021 15:01:28 |
| User entered 'No (N)' reason for change: Data Entry Error   | (b) (4), (b) (6)      | 15 Mar 2021 15:01:28 |
| User entered 'Yes (Y)'  | (b) (4), (b) (6)      | 25 Feb 2021 21:24:23 |

**US3712308**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)            | 14 Apr 2021 06:18:26 |
| User signature succeeded.                              | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered empty; reason for change Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 15:01:28 |
| User entered '18 Feb 2021'                             | (b) (4), (b) (6)            | 25 Feb 2021 21:24:23 |

US3712308

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:35

[Please select one status for the follow-up contact](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 14 Apr 2021 06:18:26 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered empty; reason for change Data Entry Error                                 | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 15:01:31 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error | (b) (4), (b) (6)            | 15 Mar 2021 15:01:28 |
| User entered 'Contact Made (CONTACT MADE)'   | (b) (4), (b) (6)            | 25 Feb 2021 21:24:23 |

**US3712308**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 14 Apr 2021 06:18:26 |
| User signature succeeded.   | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered 'subject in illness visit' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 15:01:28 |
| User entered empty.   | (b) (4), (b) (6)            | 25 Feb 2021 21:24:23 |

US3712308

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 06:18:26 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:28:12 |

**US3712308**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:26 |
| User entered '1'  | System           | 25 Feb 2021 21:28:12 |

**US3712308**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 06:18:26 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Mar 2021 20:22:42 |

US3712308

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:23:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 06:18:26 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '22 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 23 Mar 2021 20:22:42 |

**US3712308**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 14 Apr 2021 06:18:26 |
| User signature succeeded.                  | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 23 Mar 2021 20:22:42 |

**US3712308**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 06:18:26 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 23 Mar 2021 20:22:42 |

US3712308

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 06:18:26 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Mar 2021 20:22:47 |

**US3712308**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 06:18:26 |
| User entered '1'  | System           | 23 Mar 2021 20:22:47 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:23:35

[Date of Contact](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 May 2021 18:14:42 |
|  |                             |                      |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 16:26:49 |
| User closed query 'Please enter the covid 19 diagnostic page as well as the AE as result was posted reported on 11Jan2021' (Site from CRA).  | (b) (4), (b) (6)            | 28 Jan 2021 16:18:25 |
| Query 'Please enter the covid 19 diagnostic page as well as the AE as result was posted reported on 11Jan2021' answered with 'updating' (Site from CRA).   | (b) (4), (b) (6)            | 22 Jan 2021 17:11:37 |
| User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD has a sample date 07JAN2020 under Illness Visit Day1 which is missing in EDC. In EDC, COVID-19 Assessments page is initiated with a date of 06Jan2021. Please review Preclarus to verify the Year reported and update Preclarus, if applicable. Also confirm the correct date in the response and record the data in EDC. Thank you. | (b) (4), (b) (6)            | 19 Jan 2021 12:54:38 |
| ' (Site from DM).  |                             |                      |
| Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD has a sample date 07JAN2020 under Illness Visit Day1 which is missing in EDC. In EDC, COVID-19 Assessments page is initiated with a date of 06Jan2021. Please review Preclarus to verify the Year reported and update Preclarus, if applicable. Also confirm the correct date in the response and record the data in EDC. Thank you.             | (b) (4), (b) (6)            | 14 Jan 2021 13:20:56 |
| ' answered with 'updated' (Site from DM).  |                             |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:23:35

[Date of Contact](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD has a sample date 07JAN2020 under Illness Visit Day1 which is missing in EDC. In EDC, COVID-19 Assessments page is initiated with a date of 06Jan2021. Please review Preclarus to verify the Year reported and update Preclarus, if applicable. Also confirm the correct date in the response and record the data in EDC. Thank you.<br /><br />' (Site from DM). | (b) (4), (b) (6) | 13 Jan 2021 09:29:50 |
| User opened query 'Please enter the covid 19 diagnostic page as well as the AE as result was posted reported on 11Jan2021' (Site from CRA).   | (b) (4), (b) (6) | 12 Jan 2021 18:20:26 |
| User entered '06 Jan 2021'  | (b) (4), (b) (6) | 07 Jan 2021 20:58:13 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:23:35

[Time of Contact](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:42 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 16:26:49 |
|                           |                       |                      |
| User entered '15:52'      | (b) (4), (b) (6)      | 07 Jan 2021 20:58:13 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:23:35

[Date and Time of Contact \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 May 2021 18:14:42 |
|                                  |                  |                      |
|                                  |                  |                      |
| User entered '06 Jan 2021 15:52' | System           | 07 Jan 2021 20:58:13 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:23:35

[Type of Contact](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 03 May 2021 18:14:42 |
|   |                       |                      |
|   |                       |                      |
| User signature succeeded.   | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|   | (b) (4)               |                      |
| DataPoint Verified.   | (b) (4), (b) (6)      | 10 Feb 2021 20:36:42 |
|   |                       |                      |
| User closed query 'Please confirm, per eCRF guidelines, if subject contacted the site, this should be "safety call"' (Site from CRA).             | (b) (4), (b) (6)      | 10 Feb 2021 20:36:39 |
|   |                       |                      |
| Query 'Please confirm, per eCRF guidelines, if subject contacted the site, this should be "safety call"' answered with 'updated' (Site from CRA). | (b) (4), (b) (6)      | 09 Feb 2021 19:39:39 |
|   |                       |                      |
| DataPoint Un-verified.  | (b) (4), (b) (6)      | 09 Feb 2021 19:39:34 |
|   |                       |                      |
| User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error  | (b) (4), (b) (6)      | 09 Feb 2021 19:39:34 |
|   |                       |                      |
| DataPoint Verified.   | (b) (4), (b) (6)      | 28 Jan 2021 16:26:49 |
|   |                       |                      |
| User opened query 'Please confirm, per eCRF guidelines, if subject contacted the site, this should be "safety call"' (Site from CRA).             | (b) (4), (b) (6)      | 28 Jan 2021 16:26:46 |
|   |                       |                      |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'  | (b) (4), (b) (6)      | 07 Jan 2021 20:58:13 |
|   |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:23:35

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:42 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 16:26:49 |
|                           |                       |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 07 Jan 2021 20:58:13 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                              |                       |                      |
|                              |                       |                      |
| User signature succeeded.    | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                              | (b) (4)               |                      |
| User entered 'Day 1 (Day 1)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                              |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered '04 Jan 2021' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|   |                       |                      |
|   |                       |                      |
| User signature succeeded.                           | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|   | (b) (4)               |                      |
| DataPoint Verified.                                 | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|   |                       |                      |
| User entered missing code ND - Not Done; reason for | (b) (4), (b) (6)      | 22 Jan 2021 17:14:55 |
| change Data Entry Error                             |                       |                      |
| User entered empty.                                 | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|   |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                     |                  |                      |
|                     |                  |                      |
|                     |                  |                      |
| User entered '%'    | System           | 22 Jan 2021 17:14:55 |
| User entered empty. | System           | 07 Jan 2021 20:59:13 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|   |                       |                      |
|   |                       |                      |
| User signature succeeded.                           | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|   | (b) (4)               |                      |
| DataPoint Verified.                                 | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|   |                       |                      |
| User entered missing code ND - Not Done; reason for | (b) (4), (b) (6)      | 22 Jan 2021 17:14:55 |
| change Data Entry Error                             |                       |                      |
| User entered empty.                                 | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|   |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:41:36 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 20:59:13 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                              |                       |                      |
|                              |                       |                      |
| User signature succeeded.    | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                              | (b) (4)               |                      |
| User entered 'Day 2 (Day 2)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                              |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered '05 Jan 2021' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|   |                       |                      |
|   |                       |                      |
| User signature succeeded.                           | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|   | (b) (4)               |                      |
| DataPoint Verified.                                 | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|   |                       |                      |
| User entered missing code ND - Not Done; reason for | (b) (4), (b) (6)      | 22 Jan 2021 17:16:36 |
| change Data Entry Error                             |                       |                      |
| User entered empty.                                 | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|   |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                     |                  |                      |
|                     |                  |                      |
|                     |                  |                      |
| User entered '%'    | System           | 22 Jan 2021 17:16:36 |
| User entered empty. | System           | 07 Jan 2021 21:00:07 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|   |                       |                      |
|   |                       |                      |
| User signature succeeded.                           | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|   | (b) (4)               |                      |
| DataPoint Verified.                                 | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|   |                       |                      |
| User entered missing code ND - Not Done; reason for | (b) (4), (b) (6)      | 22 Jan 2021 17:16:36 |
| change Data Entry Error                             |                       |                      |
| User entered empty.                                 | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|   |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 May 2021 18:14:49 |
|   |                             |                      |
|   |                             |                      |
| User signature succeeded.   | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 15:17:09 |
| User closed query 'Please confirm, as this began on 06Jan2021 per source. If confirmed, please mark none here. ' (Site from CRA).             | (b) (4), (b) (6)            | 10 Feb 2021 15:17:00 |
| Query 'Please confirm, as this began on 06Jan2021 per source. If confirmed, please mark none here. ' answered with 'updated' (Site from CRA). | (b) (4), (b) (6)            | 09 Feb 2021 19:41:33 |
| DataPoint Un-verified.  | (b) (4), (b) (6)            | 09 Feb 2021 19:41:27 |
| User entered 'None (None)' reason for change: Data Entry Error  | (b) (4), (b) (6)            | 09 Feb 2021 19:41:27 |
| DataPoint Verified.   | (b) (4), (b) (6)            | 28 Jan 2021 16:48:37 |
| User opened query 'Please confirm, as this began on 06Jan2021 per source. If confirmed, please mark none here. ' (Site from CRA).             | (b) (4), (b) (6)            | 28 Jan 2021 16:46:50 |
| User entered 'Mild (Mild)'  | (b) (4), (b) (6)            | 07 Jan 2021 21:00:07 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 May 2021 18:14:49 |
|   |                             |                      |
|   |                             |                      |
| User signature succeeded.   | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 15:17:06 |
| User closed query 'Please confirm, as this began on 06Jan2021, per source. If confirmed, please mark none here.' (Site from CRA).             | (b) (4), (b) (6)            | 10 Feb 2021 15:17:03 |
| Query 'Please confirm, as this began on 06Jan2021, per source. If confirmed, please mark none here.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6)            | 09 Feb 2021 19:41:38 |
| DataPoint Un-verified.  | (b) (4), (b) (6)            | 09 Feb 2021 19:41:27 |
| User entered 'None (None)' reason for change: Data Entry Error  | (b) (4), (b) (6)            | 09 Feb 2021 19:41:27 |
| DataPoint Verified.   | (b) (4), (b) (6)            | 28 Jan 2021 16:48:37 |
| User opened query 'Please confirm, as this began on 06Jan2021, per source. If confirmed, please mark none here.' (Site from CRA).             | (b) (4), (b) (6)            | 28 Jan 2021 16:47:46 |
| User entered 'Mild (Mild)'  | (b) (4), (b) (6)            | 07 Jan 2021 21:00:07 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

Runny Nose (Rhinorrhea)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:48:37 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:00:07 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                              |                       |                      |
|                              |                       |                      |
| User signature succeeded.    | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                              | (b) (4)               |                      |
| User entered 'Day 3 (Day 3)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                              |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered '06 Jan 2021' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|   |                       |                      |
|   |                       |                      |
| User signature succeeded.                           | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|   | (b) (4)               |                      |
| DataPoint Verified.                                 | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|   |                       |                      |
| User entered missing code ND - Not Done; reason for | (b) (4), (b) (6)      | 22 Jan 2021 17:16:43 |
| change Data Entry Error                             |                       |                      |
| User entered empty.                                 | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|   |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                     |                  |                      |
|                     |                  |                      |
|                     |                  |                      |
| User entered '%'    | System           | 22 Jan 2021 17:16:43 |
| User entered empty. | System           | 07 Jan 2021 21:01:08 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.                                   | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|   |                       |                      |
|   |                       |                      |
| User signature succeeded.                           | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|   | (b) (4)               |                      |
| DataPoint Verified.                                 | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|   |                       |                      |
| User entered missing code ND - Not Done; reason for | (b) (4), (b) (6)      | 22 Jan 2021 17:16:43 |
| change Data Entry Error                             |                       |                      |
| User entered empty.                                 | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|   |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

Runny Nose (Rhinorrhea)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                                      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| DataPoint Verified.  | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|  |                       |                      |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|  |                       |                      |
| User entered 'None (None)'                                     | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 16:58:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:01:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                              |                       |                      |
|                              |                       |                      |
| User signature succeeded.    | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                              | (b) (4)               |                      |
| User entered 'Day 4 (Day 4)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                              |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered '07 Jan 2021' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|   |                       |                      |
|   |                       |                      |
| User signature succeeded.                             | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|   | (b) (4)               |                      |
| DataPoint Verified.                                   | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|   |                       |                      |
| User entered '98' reason for change: Data Entry Error | (b) (4), (b) (6)      | 22 Jan 2021 17:17:01 |
|   |                       |                      |
| User entered empty.                                   | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|   |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                     |                  |                      |
|                     |                  |                      |
|                     |                  |                      |
| User entered '%'    | System           | 22 Jan 2021 17:17:01 |
| User entered empty. | System           | 07 Jan 2021 21:04:08 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                           |                       |                      |
| User entered '37.2' C     | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 17:03:20 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 07 Jan 2021 21:04:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                              |                       |                      |
|                              |                       |                      |
|                              |                       |                      |
| User signature succeeded.    | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                              | (b) (4)               |                      |
| User entered 'Day 5 (Day 5)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                              |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered '08 Jan 2021' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                           |                       |                      |
| User entered '98'         | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 22 Jan 2021 17:18:18 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                           |                       |                      |
| User entered '99.4' F     | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

Diarrhea

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 May 2021 18:14:49 |
|  |                             |                      |
|  |                             |                      |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.  | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 15:17:27 |
| User closed query 'Please confirm, as mild seems to be noted in symptom log and illness contact.' (Site from CRA).             | (b) (4), (b) (6)            | 10 Feb 2021 15:17:25 |
| Query 'Please confirm, as mild seems to be noted in symptom log and illness contact.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6)            | 09 Feb 2021 19:44:04 |
| DataPoint Un-verified.   | (b) (4), (b) (6)            | 09 Feb 2021 19:43:58 |
| User entered 'Mild (Mild)' reason for change: Data Entry Error   | (b) (4), (b) (6)            | 09 Feb 2021 19:43:58 |
| DataPoint Verified.  | (b) (4), (b) (6)            | 28 Jan 2021 17:14:38 |
| User opened query 'Please confirm, as mild seems to be noted in symptom log and illness contact.' (Site from CRA).             | (b) (4), (b) (6)            | 28 Jan 2021 17:10:05 |
| User entered 'None (None)'   | (b) (4), (b) (6)            | 22 Jan 2021 17:18:18 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 17:14:38 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:18:18 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                              |                       |                      |
|                              |                       |                      |
|                              |                       |                      |
| User signature succeeded.    | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                              | (b) (4)               |                      |
| User entered 'Day 6 (Day 6)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                              |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered '09 Jan 2021' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                           |                       |                      |
| User entered '97'         | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 22 Jan 2021 17:19:22 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                           |                       |                      |
| User entered '98.6' F     | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 18:30:32 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:19:22 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                              |                       |                      |
|                              |                       |                      |
| User signature succeeded.    | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                              | (b) (4)               |                      |
| User entered 'Day 7 (Day 7)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                              |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered '10 Jan 2021' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '100'        | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                           |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 22 Jan 2021 17:20:33 |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '98.0' F     | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:20:33 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                              |                       |                      |
|                              |                       |                      |
|                              |                       |                      |
| User signature succeeded.    | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                              | (b) (4)               |                      |
| User entered 'Day 8 (Day 8)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                              |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered '11 Jan 2021' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '98'         | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 22 Jan 2021 17:24:41 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '97.3' F     | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:24:41 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                              |                       |                      |
|                              |                       |                      |
| User signature succeeded.    | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                              | (b) (4)               |                      |
| User entered 'Day 9 (Day 9)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                              |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered '12 Jan 2021' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '97'         | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 22 Jan 2021 17:25:55 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '98.1' F     | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:25:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                |                       |                      |
|                                |                       |                      |
|                                |                       |                      |
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                | (b) (4)               |                      |
| User entered 'Day 10 (Day 10)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                                |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered '13 Jan 2021' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '96'         | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 22 Jan 2021 17:26:54 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '97.0' F     | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:26:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                |                       |                      |
|                                |                       |                      |
|                                |                       |                      |
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                | (b) (4)               |                      |
| User entered 'Day 11 (Day 11)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                                |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered '14 Jan 2021' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '96'         | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 22 Jan 2021 17:27:27 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '98.1' F     | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:27:27 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                |                       |                      |
|                                |                       |                      |
|                                |                       |                      |
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                | (b) (4)               |                      |
| User entered 'Day 12 (Day 12)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                                |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered '15 Jan 2021' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '88'         | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 22 Jan 2021 17:28:16 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '98.0' F     | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                              | User                  | Time (GMT)           |
|------------------------------------|-----------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                    |                       |                      |
|                                    |                       |                      |
| User signature succeeded.          | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                    | (b) (4)               |                      |
| DataPoint Verified.                | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                                    |                       |                      |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                                    |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                              | User                  | Time (GMT)           |
|------------------------------------|-----------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                    |                       |                      |
|                                    |                       |                      |
| User signature succeeded.          | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                    | (b) (4)               |                      |
| DataPoint Verified.                | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                                    |                       |                      |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                                    |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:16 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                |                       |                      |
|                                |                       |                      |
|                                |                       |                      |
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                | (b) (4)               |                      |
| User entered 'Day 13 (Day 13)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                                |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered '16 Jan 2021' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '90'         | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 22 Jan 2021 17:28:59 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '98.7' F     | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                              | User                  | Time (GMT)           |
|------------------------------------|-----------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                    |                       |                      |
|                                    |                       |                      |
| User signature succeeded.          | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                    | (b) (4)               |                      |
| DataPoint Verified.                | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                                    |                       |                      |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                                    |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                              | User                  | Time (GMT)           |
|------------------------------------|-----------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                    |                       |                      |
|                                    |                       |                      |
| User signature succeeded.          | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.                | (b) (4)               |                      |
|                                    | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                                    |                       |                      |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                                    |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

Runny Nose (Rhinorrhea)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:28:59 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                |                       |                      |
|                                |                       |                      |
|                                |                       |                      |
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                | (b) (4)               |                      |
| User entered 'Day 14 (Day 14)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                                |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered '17 Jan 2021' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '90'         | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 22 Jan 2021 17:30:24 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '97.2' F     | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                              | User                  | Time (GMT)           |
|------------------------------------|-----------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                    |                       |                      |
|                                    |                       |                      |
| User signature succeeded.          | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                    | (b) (4)               |                      |
| DataPoint Verified.                | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                                    |                       |                      |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                                    |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                              | User                  | Time (GMT)           |
|------------------------------------|-----------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                    |                       |                      |
|                                    |                       |                      |
| User signature succeeded.          | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.                | (b) (4)               |                      |
|                                    | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                                    |                       |                      |
| User entered 'Moderate (Moderate)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                                    |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:30:24 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                |                       |                      |
|                                |                       |                      |
|                                |                       |                      |
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                | (b) (4)               |                      |
| User entered 'Day 15 (Day 15)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                                |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered '18 Jan 2021' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '94'         | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 22 Jan 2021 17:31:12 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '97.0' F     | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|   |                       |                      |
|   |                       |                      |
| User signature succeeded.   | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|   | (b) (4)               |                      |
| DataPoint Verified.   | (b) (4), (b) (6)      | 10 Feb 2021 15:18:16 |
|   |                       |                      |
| User closed query 'Please confirm, per symptom log on illness day 18Jan2021 cough was still ongoing. If confirmed, please update.' (Site from CRA).             | (b) (4), (b) (6)      | 10 Feb 2021 15:18:14 |
| Query 'Please confirm, per symptom log on illness day 18Jan2021 cough was still ongoing. If confirmed, please update.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6)      | 09 Feb 2021 19:44:50 |
|   |                       |                      |
| DataPoint Un-verified.  | (b) (4), (b) (6)      | 09 Feb 2021 19:44:44 |
|   |                       |                      |
| User entered 'Mild (Mild)' reason for change: Data Entry Error  | (b) (4), (b) (6)      | 09 Feb 2021 19:44:44 |
|   |                       |                      |
| DataPoint Verified.   | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|   |                       |                      |
| User opened query 'Please confirm, per symptom log on illness day 18Jan2021 cough was still ongoing. If confirmed, please update.' (Site from CRA).             | (b) (4), (b) (6)      | 28 Jan 2021 19:01:50 |
|   |                       |                      |
| User entered 'None (None)'  | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|   |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:31:12 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                |                       |                      |
|                                |                       |                      |
|                                |                       |                      |
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                | (b) (4)               |                      |
| User entered 'Day 16 (Day 16)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                                |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

Date

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 May 2021 18:14:49 |
|  |                             |                      |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User closed query 'Per Protocol page 127, the Participant will have daily telemedicine visits for 14 days or until symptoms resolve, whichever is longer. It appears per source and EDC symptoms were not resolved on 19Jan2021. Source is in the subject's binder for 20Jan2021-24Jan2021. Please add to Symptom Log in EDC and please state why telemedicine visits did not continue past 24Jan2021, since symptoms had not resolved on hat date according to source.' (Site from CRA).            | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 04:23:01 |
| Query 'Per Protocol page 127, the Participant will have daily telemedicine visits for 14 days or until symptoms resolve, whichever is longer. It appears per source and EDC symptoms were not resolved on 19Jan2021. Source is in the subject's binder for 20Jan2021-24Jan2021. Please add to Symptom Log in EDC and please state why telemedicine visits did not continue past 24Jan2021, since symptoms had not resolved on hat date according to source.' answered with 'adde3d' (Site from CRA). | (b) (4), (b) (6)            | 12 Feb 2021 18:46:40 |
| User opened query 'Per Protocol page 127, the Participant will have daily telemedicine visits for 14 days or until symptoms resolve, whichever is longer. It appears per source and EDC symptoms were not resolved on 19Jan2021. Source is in the subject's binder for 20Jan2021-24Jan2021. Please add to Symptom Log in EDC and please state why telemedicine visits did not continue past 24Jan2021, since symptoms had not resolved on hat date according to source.' (Site from CRA).            | (b) (4), (b) (6)            | 10 Feb 2021 22:04:50 |
| DataPoint Verified.  | (b) (4), (b) (6)            | 28 Jan 2021 19:02:27 |
| User entered '19 Jan 2021'   | (b) (4), (b) (6)            | 22 Jan 2021 17:33:08 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '94'         | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 22 Jan 2021 17:33:08 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                           |                       |                      |
| User entered '98.4' F     | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

Runny Nose (Rhinorrhea)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:02:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 22 Jan 2021 17:33:08 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                |                       |                      |
|                                |                       |                      |
|                                |                       |                      |
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                | (b) (4)               |                      |
| User entered 'Day 17 (Day 17)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                                |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:40:15 |
|                            |                       |                      |
| User entered '20 Jan 2021' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 25 Feb 2021 20:40:18 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 25 Feb 2021 20:40:20 |
|                           |                       |                      |
| User entered '92'         | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 12 Feb 2021 18:37:55 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 25 Feb 2021 20:40:22 |
|                           |                       |                      |
| User entered '98.0' F     | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:40:29 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:41:10 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:41:09 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 20:41:06 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:41:04 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 20:41:02 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:41:01 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:40:59 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 20:40:56 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:40:52 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:40:50 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:40:48 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:40:38 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:40:45 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:40:43 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:40:41 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:37:55 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                |                       |                      |
|                                |                       |                      |
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                | (b) (4)               |                      |
| User entered 'Day 18 (Day 18)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                                |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 20:41:23 |
|                            |                       |                      |
| User entered '21 Jan 2021' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 25 Feb 2021 20:41:25 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 25 Feb 2021 20:41:27 |
|                           |                       |                      |
| User entered '93'         | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 12 Feb 2021 18:39:02 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 25 Feb 2021 20:41:29 |
|                           |                       |                      |
| User entered '98.2' F     | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:11:40 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:12:11 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:12:09 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:12:08 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:12:06 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:12:04 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:12:02 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:12:00 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:11:59 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:11:57 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:11:55 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

Runny Nose (Rhinorrhea)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:11:53 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:11:46 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:11:48 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:11:50 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:11:51 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:02 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                |                       |                      |
|                                |                       |                      |
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                | (b) (4)               |                      |
| User entered 'Day 19 (Day 19)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                                |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:12:25 |
|                            |                       |                      |
| User entered '22 Jan 2021' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 25 Feb 2021 21:12:27 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 25 Feb 2021 21:12:29 |
|                           |                       |                      |
| User entered '92'         | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 12 Feb 2021 18:39:54 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 25 Feb 2021 21:12:31 |
|                           |                       |                      |
| User entered '97.4' F     | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:12:35 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:12:47 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:12:49 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:12:50 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:12:52 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:12:54 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:12:56 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:12:58 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:13:00 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:13:01 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:13:04 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:13:05 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:12:40 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:13:07 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:13:10 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:13:12 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:39:54 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                |                       |                      |
|                                |                       |                      |
|                                |                       |                      |
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                | (b) (4)               |                      |
| User entered 'Day 20 (Day 20)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                                |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:13:57 |
|                            |                       |                      |
| User entered '23 Jan 2021' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 25 Feb 2021 21:13:59 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 25 Feb 2021 21:14:01 |
|                           |                       |                      |
| User entered '92'         | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 12 Feb 2021 18:44:56 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User closed query 'Per CDM: Per sponsor review, please confirm unit for temperature. ' (Site from DM).             | (b) (4), (b) (6)      | 26 Feb 2021 20:15:19 |
|  |                       |                      |
| DataPoint Verified.  | (b) (4), (b) (6)      | 25 Feb 2021 21:14:05 |
|  |                       |                      |
| Query 'Per CDM: Per sponsor review, please confirm unit for temperature. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6)      | 24 Feb 2021 20:53:50 |
|  |                       |                      |
| User entered '98.1' F reason for change: Data Entry Error  | (b) (4), (b) (6)      | 24 Feb 2021 20:53:40 |
|  |                       |                      |
| User opened query 'Per CDM: Per sponsor review, please confirm unit for temperature. ' (Site from DM).             | (b) (4), (b) (6)      | 24 Feb 2021 00:33:54 |
|  |                       |                      |
| User entered '98.1' C  | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:14:10 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:14:35 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:14:36 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:14:39 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:14:42 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:14:44 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:14:46 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:14:48 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:14:50 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:14:52 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:14:54 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

Runny Nose (Rhinorrhea)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:14:56 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:14:24 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:14:26 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:14:28 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:14:31 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:44:56 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 May 2021 18:14:49 |
|   |                             |                      |
| User closed query 'Subject was still experiencing symptoms, which means that the symptom log should have continued. Source states that a telemedicine visit occurred on 26Jan2021, please add that to the symptom log, including adding 25Jan2021 as "Assessment Not Done".' (Site from CRA).           | (b) (4), (b) (6)            | 21 Apr 2021 15:22:34 |
| User signature succeeded.   | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| Query 'Subject was still experiencing symptoms, which means that the symptom log should have continued. Source states that a telemedicine visit occurred on 26Jan2021, please add that to the symptom log, including adding 25Jan2021 as "Assessment Not Done".' answered with 'added' (Site from CRA). | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 20:10:11 |
| User opened query 'Subject was still experiencing symptoms, which means that the symptom log should have continued. Source states that a telemedicine visit occurred on 26Jan2021, please add that to the symptom log, including adding 25Jan2021 as "Assessment Not Done".' (Site from CRA).           | (b) (4), (b) (6)            | 25 Feb 2021 21:19:15 |
| User entered 'Day 21 (Day 21)'  | (b) (4), (b) (6)            | 12 Feb 2021 18:45:57 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:15:08 |
|                            |                       |                      |
| User entered '24 Jan 2021' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 25 Feb 2021 21:15:10 |
|                           |                       |                      |
| User entered '0'          | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 25 Feb 2021 21:15:13 |
|                           |                       |                      |
| User entered '94'         | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 12 Feb 2021 18:45:57 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 25 Feb 2021 21:15:14 |
|                           |                       |                      |
| User entered '97.0' F     | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:15:25 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:15:27 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:15:59 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:15:57 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:15:55 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:15:53 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:15:52 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:15:50 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:15:48 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:15:46 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:15:44 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:15:42 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:15:32 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 25 Feb 2021 21:15:34 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:15:36 |
|                            |                       |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (21)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 25 Feb 2021 21:15:39 |
|                            |                       |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 12 Feb 2021 18:45:57 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                |                       |                      |
|                                |                       |                      |
|                                |                       |                      |
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                | (b) (4)               |                      |
| User entered 'Day 22 (Day 22)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|                                |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered '25 Jan 2021' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                            | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered '1' reason for change: Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered '0'                                     | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered '98'                                      | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                     |                  |                      |
|                     |                  |                      |
|                     |                  |                      |
| User entered empty. | System           | 10 Mar 2021 20:10:59 |
| User entered '%'    | System           | 10 Mar 2021 20:09:06 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered '97.3' F                                  | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'None (None)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'Mild (Mild)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'Mild (Mild)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'Mild (Mild)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'Mild (Mild)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'Mild (Mild)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'Mild (Mild)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'Mild (Mild)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'Mild (Mild)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'Mild (Mild)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'Mild (Mild)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'Mild (Mild)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'None (None)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'None (None)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'None (None)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (22)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                              | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)      | 10 Mar 2021 20:10:59 |
|  |                       |                      |
| User entered 'Mild (Mild)'                             | (b) (4), (b) (6)      | 10 Mar 2021 20:09:06 |
|  |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Symptom Day](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                                |                       |                      |
|                                |                       |                      |
|                                |                       |                      |
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                | (b) (4)               |                      |
| User entered 'Day 23 (Day 23)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                                |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Date](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered '26 Jan 2021' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Assessment Not Done](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| User entered '0'          | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| User entered '96'         | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[O2 Saturation Units](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 18:14:49 |
|                   |                  |                      |
|                   |                  |                      |
| User entered '%'  | System           | 10 Mar 2021 20:09:38 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Temperature](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                           |                       |                      |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| User entered '98.2' F     | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Chills](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Cough](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Shortness of Breath](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Difficulty Breathing](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Fatigue](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Muscle Aches \(Myalgia\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Body Aches](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Headache](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Taste](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[New Loss of Smell](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Nasal Congestion](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Runny Nose \(Rhinorrhea\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Nausea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Vomiting](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Diarrhea](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'None (None)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Symptom Log (23)

Generated On: 12 Aug 2021 13:23:35

[Sore Throat](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:49 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'Mild (Mild)' | (b) (4), (b) (6)      | 10 Mar 2021 20:09:38 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:35

[Date of Visit](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:57 |
|                            |                       |                      |
|                            |                       |                      |
| Data entry locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:55 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:17:28 |
|                            |                       |                      |
| User entered '07 Jan 2021' | (b) (4), (b) (6)      | 14 Jan 2021 13:20:36 |
|                            |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:35

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:57 |
|                           |                       |                      |
| Data entry locked.        | (b) (4), (b) (6)      | 03 May 2021 18:14:55 |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:17:28 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 14 Jan 2021 13:20:36 |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:35

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 May 2021 18:14:57 |
|   |                             |                      |
| Data entry locked.  | (b) (4), (b) (6)            | 03 May 2021 18:14:55 |
|   |                             |                      |
| User signature succeeded.   | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).             | (b) (4)<br>(b) (4), (b) (6) | 11 Feb 2021 10:47:17 |
| DataPoint Verified.   | (b) (4), (b) (6)            | 10 Feb 2021 21:07:53 |
| User closed query 'Please confirm, as subject did test positive at 07Jan2021 illness visit. iF confirmed, please update.' (Site from CRA).  | (b) (4), (b) (6)            | 10 Feb 2021 21:07:51 |
| Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'updated' (Site from System). | (b) (4), (b) (6)            | 09 Feb 2021 19:38:30 |
| Query 'Please confirm, as subject did test positive at 07Jan2021 illness visit. iF confirmed, please update.' answered with 'updated' (Site from CRA).  | (b) (4), (b) (6)            | 09 Feb 2021 19:38:18 |
| User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).             | System                      | 09 Feb 2021 19:38:11 |
| DataPoint Un-verified.  | (b) (4), (b) (6)            | 09 Feb 2021 19:38:11 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | (b) (4), (b) (6)            | 09 Feb 2021 19:38:11 |
| DataPoint Verified.   | (b) (4), (b) (6)            | 28 Jan 2021 19:17:28 |
| User opened query 'Please confirm, as subject did test positive at 07Jan2021 illness visit. iF confirmed, please update.' (Site from CRA).  | (b) (4), (b) (6)            | 28 Jan 2021 17:26:10 |
| User entered 'No (N)'   | (b) (4), (b) (6)            | 14 Jan 2021 13:20:36 |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:35

[Date of Test](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 18:14:57 |
|                            |                       |                      |
|                            |                       |                      |
| Data entry locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:55 |
|                            |                       |                      |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| DataPoint Verified.        | (b) (4), (b) (6)      | 28 Jan 2021 19:17:28 |
|                            |                       |                      |
| User entered '07 Jan 2021' | (b) (4), (b) (6)      | 14 Jan 2021 13:20:36 |
|                            |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:35

[Type of Test Performed](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 03 May 2021 18:14:57 |
|  |                       |                      |
|  |                       |                      |
| Data entry locked.                                       | (b) (4), (b) (6)      | 03 May 2021 18:14:55 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                                | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| DataPoint Verified.                                      | (b) (4), (b) (6)      | 28 Jan 2021 19:17:28 |
|  |                       |                      |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | (b) (4), (b) (6)      | 14 Jan 2021 13:20:36 |
|  |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:35

[Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:57 |
|                           |                       |                      |
|                           |                       |                      |
| Data entry locked.        | (b) (4), (b) (6)      | 03 May 2021 18:14:55 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:17:28 |
|                           |                       |                      |
| User entered empty.       | (b) (4), (b) (6)      | 14 Jan 2021 13:20:36 |
|                           |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:35

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:57 |
|                           |                       |                      |
|                           |                       |                      |
| Data entry locked.        | (b) (4), (b) (6)      | 03 May 2021 18:14:55 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:17:28 |
|                           |                       |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 14 Jan 2021 13:20:36 |
|                           |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:35

[Lab/ Institution Test Performed](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:57 |
|                           |                       |                      |
|                           |                       |                      |
| Data entry locked.        | (b) (4), (b) (6)      | 03 May 2021 18:14:55 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:17:28 |
|                           |                       |                      |
| User entered empty.       | (b) (4), (b) (6)      | 14 Jan 2021 13:20:36 |
|                           |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:23:35

[CLIA Certified?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:14:57 |
|                           |                       |                      |
|                           |                       |                      |
| Data entry locked.        | (b) (4), (b) (6)      | 03 May 2021 18:14:55 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 28 Jan 2021 19:17:28 |
|                           |                       |                      |
| User entered empty.       | (b) (4), (b) (6)      | 14 Jan 2021 13:20:36 |
|                           |                       |                      |

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Form: COVID Diagnostic Test

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COVID-19 Positive (CSA Programming Field Only)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 May 2021 18:14:57 |
|                    |                  |                      |
|                    |                  |                      |
| Data entry locked. | (b) (4), (b) (6) | 03 May 2021 18:14:55 |
|                    |                  |                      |
|                    |                  |                      |
| User entered '1'   | System           | 09 Feb 2021 19:38:11 |
| User entered '0'   | System           | 14 Jan 2021 13:20:36 |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

[Start Date](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered empty.       | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

[End Date](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered empty.       | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

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Form: Covid-19 Severity Assessment

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[Respiratory Rate](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered empty.       | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

Did the subject have Heart Rate  $\geq$  125 beats per minute

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

[Start Date](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered empty.       | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

[End Date](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered empty.       | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

[Heart Rate](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered empty.       | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|  | (b) (4), (b) (6)      |                      |
|  | (b) (4), (b) (6)      |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.  | (b) (4), (b) (6)      | 25 Feb 2021 21:31:24 |
| User closed query 'Please ensure to enter the O2 levels in the below fields.' (Site from CRA).   | (b) (4), (b) (6)      | 25 Feb 2021 21:31:22 |
| Query 'Please ensure to enter the O2 levels in the below fields.' answered with 'updated' (Site from CRA).   | (b) (4), (b) (6)      | 24 Feb 2021 20:50:31 |
| User opened query 'Please ensure to enter the O2 levels in the below fields.' (Site from CRA).   | (b) (4), (b) (6)      | 23 Feb 2021 22:55:26 |
| User closed query 'Please review source and revise if needed. On 15-17Jan2021, the source states that the subject reported an O2 Saturation < 93%.' (Site from CRA).             | (b) (4), (b) (6)      | 23 Feb 2021 22:50:45 |
| Query 'Please review source and revise if needed. On 15-17Jan2021, the source states that the subject reported an O2 Saturation < 93%.' answered with 'UPDATED' (Site from CRA). | (b) (4), (b) (6)      | 12 Feb 2021 18:30:30 |
| User entered 'Yes (Y)' reason for change: Data Entry Error   | (b) (4), (b) (6)      | 12 Feb 2021 18:30:23 |
| User opened query 'Please review source and revise if needed. On 15-17Jan2021, the source states that the subject reported an O2 Saturation < 93%.' (Site from CRA).             | (b) (4), (b) (6)      | 10 Feb 2021 21:19:04 |
| DataPoint Un-verified.   | (b) (4), (b) (6)      | 10 Feb 2021 21:17:01 |
| DataPoint Verified.  | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
| User entered 'No (N)'  | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

[Start Date](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                                      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| DataPoint Verified.  | (b) (4), (b) (6)      | 25 Feb 2021 21:31:30 |
|  |                       |                      |
| DataPoint Un-verified.   | (b) (4), (b) (6)      | 24 Feb 2021 20:50:22 |
|  |                       |                      |
| User entered '15 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6)      | 24 Feb 2021 20:50:22 |
|  |                       |                      |
| DataPoint Verified.  | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|  |                       |                      |
| User entered empty.  | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|  |                       |                      |

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Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

[End Date](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                                      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.  | (b) (4)               |                      |
|  | (b) (4), (b) (6)      | 25 Feb 2021 21:31:32 |
| DataPoint Un-verified.   | (b) (4), (b) (6)      | 24 Feb 2021 20:50:22 |
| User entered '17 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6)      | 24 Feb 2021 20:50:22 |
| DataPoint Verified.  | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
| User entered empty.  | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|  |                       |                      |

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

[Oxygen Saturation](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|   |                       |                      |
|   |                       |                      |
| User signature succeeded.                             | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.                                   | (b) (4)               |                      |
|   | (b) (4), (b) (6)      | 25 Feb 2021 21:31:55 |
| DataPoint Un-verified.                                | (b) (4), (b) (6)      | 24 Feb 2021 20:50:22 |
| User entered '88' reason for change: Data Entry Error | (b) (4), (b) (6)      | 24 Feb 2021 20:50:22 |
| DataPoint Verified.                                   | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
| User entered empty.                                   | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|   |                       |                      |

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Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

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[Start Date](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                                      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| DataPoint Verified.  | (b) (4), (b) (6)      | 25 Feb 2021 21:32:05 |
|  |                       |                      |
| User entered empty; reason for change Data Entry Error         | (b) (4), (b) (6)      | 24 Feb 2021 20:50:22 |
|  |                       |                      |
| DataPoint Un-verified.   | (b) (4), (b) (6)      | 12 Feb 2021 18:31:32 |
|  |                       |                      |
| User entered '15 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6)      | 12 Feb 2021 18:31:32 |
|  |                       |                      |
| DataPoint Verified.  | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|  |                       |                      |
| User entered empty.  | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|  |                       |                      |

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[End Date](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|  |                       |                      |
|  |                       |                      |
|  |                       |                      |
| User signature succeeded.                                      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| DataPoint Verified.  | (b) (4), (b) (6)      | 25 Feb 2021 21:32:10 |
|  |                       |                      |
| User entered empty; reason for change Data Entry Error         | (b) (4), (b) (6)      | 24 Feb 2021 20:50:22 |
|  |                       |                      |
| DataPoint Un-verified.   | (b) (4), (b) (6)      | 12 Feb 2021 18:31:32 |
|  |                       |                      |
| User entered '17 Jan 2021' reason for change: Data Entry Error | (b) (4), (b) (6)      | 12 Feb 2021 18:31:32 |
|  |                       |                      |
| DataPoint Verified.  | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|  |                       |                      |
| User entered empty.  | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|  |                       |                      |

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[PaO2](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)            | 03 May 2021 18:15:05 |
|  |                             |                      |
|  |                             |                      |
| User signature succeeded.                              | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.                                    | (b) (4)<br>(b) (4), (b) (6) | 25 Feb 2021 21:32:11 |
| User entered empty; reason for change Data Entry Error | (b) (4), (b) (6)            | 24 Feb 2021 20:50:22 |
| DataPoint Un-verified.                                 | (b) (4), (b) (6)            | 12 Feb 2021 18:31:32 |
| User entered '90' reason for change: Data Entry Error  | (b) (4), (b) (6)            | 12 Feb 2021 18:31:32 |
| DataPoint Verified.                                    | (b) (4), (b) (6)            | 10 Feb 2021 21:15:48 |
| User entered empty.                                    | (b) (4), (b) (6)            | 09 Feb 2021 19:39:00 |

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Did the subject have Respiratory failure?

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
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| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
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| User entered 'No (N)'     | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
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[Start Date](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
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[Start Date](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
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[High-Flow Oxygen?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
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| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
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[Start Date](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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[End Date](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
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[Non-Invasive Ventilation?](#)

| Audit                     | User                  | Time (GMT)           |
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[Start Date](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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[End Date](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
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[Mechanical Ventilation?](#)

| Audit                     | User                  | Time (GMT)           |
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[Start Date](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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[End Date](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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[ECMO?](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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[Start Date](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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[End Date](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
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| User entered 'No (N)'     | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
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[Start Date](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
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| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
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| User entered empty.       | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
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[End Date](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
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| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
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[Evidence of Shock Requires  
Vasopressors](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
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| Audit                     | User                  | Time (GMT)           |
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| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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[Acute Renal Dysfunction?](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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[Hepatic Dysfunction?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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[Neurologic Dysfunction?](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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| Audit                     | User                  | Time (GMT)           |
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[Clinical Evidence](#)

| Audit                     | User                  | Time (GMT)           |
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| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
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[Date of Assessment](#)

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[Radiographical Evidence](#)

| Audit                     | User                  | Time (GMT)           |
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|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

[Date of Assessment](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered empty.       | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

[Admission to an intensive care unit due to SARS-CoV-2](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

[Start Date](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered empty.       | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

US3712308

Folder: Covid-19 Assessment 06 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:23:35

[End Date](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 18:15:05 |
|                           |                       |                      |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| DataPoint Verified.       | (b) (4), (b) (6)      | 10 Feb 2021 21:15:48 |
|                           |                       |                      |
| User entered empty.       | (b) (4), (b) (6)      | 09 Feb 2021 19:39:00 |
|                           |                       |                      |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Visit](#)

| Audit                                       | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                           | (b) (4), (b) (6) | 03 May 2021 09:50:50 |
| User accepted default value 'Day 3 (Day 3)' | (b) (4), (b) (6) | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Was Saliva Collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 May 2021 09:50:50 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:39 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 May 2021 09:50:50 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:39 |
| User entered '08 Jan 2021' | (b) (4), (b) (6)            | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Visit](#)

| Audit                                       | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                           | (b) (4), (b) (6) | 03 May 2021 09:50:50 |
| User accepted default value 'Day 5 (Day 5)' | (b) (4), (b) (6) | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Was Saliva Collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 May 2021 09:50:50 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:39 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 May 2021 09:50:50 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:39 |
| User entered '11 Jan 2021' | (b) (4), (b) (6)            | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Visit](#)

| Audit                                       | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                           | (b) (4), (b) (6) | 03 May 2021 09:50:50 |
| User accepted default value 'Day 7 (Day 7)' | (b) (4), (b) (6) | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Was Saliva Collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 May 2021 09:50:50 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:39 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Date of Collection](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 May 2021 09:50:50 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:39 |
| User entered empty.       | (b) (4), (b) (6)            | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Visit](#)

| Audit                                       | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                           | (b) (4), (b) (6) | 03 May 2021 09:50:50 |
| User accepted default value 'Day 9 (Day 9)' | (b) (4), (b) (6) | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Was Saliva Collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 May 2021 09:50:50 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:39 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Date of Collection](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 May 2021 09:50:50 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:39 |
| User entered empty.       | (b) (4), (b) (6)            | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Visit](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                             | (b) (4), (b) (6) | 03 May 2021 09:50:50 |
| User accepted default value 'Day 14 (Day 14)' | (b) (4), (b) (6) | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Was Saliva Collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 May 2021 09:50:50 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:39 |
| User entered 'No (N)'     | (b) (4), (b) (6)            | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Date of Collection](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 May 2021 09:50:50 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:39 |
| User entered empty.       | (b) (4), (b) (6)            | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Visit](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                             | (b) (4), (b) (6) | 03 May 2021 09:50:50 |
| User accepted default value 'Day 21 (Day 21)' | (b) (4), (b) (6) | 22 Jan 2021 17:37:03 |

US3712308

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:23:35

[Was Saliva Collected?](#)

| Audit   | User                                      | Time (GMT)                                   |
|---|---|--|
| Data hard locked.   | (b) (4), (b) (6)                          | 03 May 2021 09:50:50                         |
| User closed query 'Please review source and revise if needed. Source states that Saliva was collected on 26Jan2021 for Illness day 21.' (Site from CRA).<br>User signature succeeded. | (b) (4), (b) (6)<br>William Smith (b) (4) | 21 Apr 2021 15:23:06<br>05 Apr 2021 00:44:24 |
| Query 'Please review source and revise if needed. Source states that Saliva was collected on 26Jan2021 for Illness day 21.' answered with 'updated' (Site from CRA).                  | (b) (4), (b) (6)                          | 10 Mar 2021 20:12:52                         |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | (b) (4), (b) (6)                          | 10 Mar 2021 20:12:38                         |
| User opened query 'Please review source and revise if needed. Source states that Saliva was collected on 26Jan2021 for Illness day 21.' (Site from CRA).<br>DataPoint Un-verified.    | (b) (4), (b) (6)                          | 10 Feb 2021 21:40:15<br>10 Feb 2021 21:39:15 |
| DataPoint Verified.   | (b) (4), (b) (6)                          | 28 Jan 2021 19:20:39                         |
| User entered 'No (N)'   | (b) (4), (b) (6)                          | 22 Jan 2021 17:37:03                         |

US3712308

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:23:35

[Date of Collection](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 May 2021 09:50:50 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26JAN2021 for Day 21 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, if no sample collected on this day then please review the preclaus data and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 05:34:07 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26JAN2021 for Day 21 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, if no sample collected on this day then please review the preclaus data and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' answered with 'updated' (Site from DM). | (b) (4), (b) (6)            | 10 Mar 2021 20:12:58 |
| User entered '26 Jan 2021' reason for change: Data Entry Error   | (b) (4), (b) (6)            | 10 Mar 2021 20:12:38 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26JAN2021 for Day 21 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, if no sample collected on this day then please review the preclaus data and update the sample details to correct subject ID and visit in PPD portal, confirm the subject ID and visit in query response, thank you.' (Site from DM).             | (b) (4), (b) (6)            | 23 Feb 2021 07:29:27 |

US3712308

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:23:35

[Date of Collection](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26JAN2021 is reported under Illness Visit Day 21 in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details, thank you.' (Site from DM). DataPoint Un-verified. | (b) (4), (b) (6) | 23 Feb 2021 07:29:27 |
|   | (b) (4), (b) (6) | 10 Feb 2021 21:39:17 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26JAN2021 is reported under Illness Visit Day 21 in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details, thank you.' answered with 'updated' (Site from DM).            | (b) (4), (b) (6) | 09 Feb 2021 19:45:21 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 26JAN2021 is reported under Illness Visit Day 21 in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details, thank you.' (Site from DM). DataPoint Verified.    | (b) (4), (b) (6) | 08 Feb 2021 06:06:36 |
|   | (b) (4), (b) (6) | 28 Jan 2021 19:20:39 |
| User entered empty.   | (b) (4), (b) (6) | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 12 Aug 2021 13:23:35**

[Visit](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                             | (b) (4), (b) (6) | 03 May 2021 09:50:50 |
| User accepted default value 'Day 28 (Day 28)' | (b) (4), (b) (6) | 22 Jan 2021 17:37:03 |

US3712308

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:23:35

[Was Saliva Collected?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 03 May 2021 09:50:50 |
| User signature succeeded.   | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User closed query 'Please review lab report. Lab report stated that Saliva Sample Day 28 was collected but the test results were inconclusive. ' (Site from CRA).             | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 23:01:41 |
| Query 'Please review lab report. Lab report stated that Saliva Sample Day 28 was collected but the test results were inconclusive. ' answered with 'u;dated' (Site from CRA). | (b) (4), (b) (6)            | 12 Feb 2021 18:52:03 |
| DataPoint Un-verified.  | (b) (4), (b) (6)            | 12 Feb 2021 18:51:59 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | (b) (4), (b) (6)            | 12 Feb 2021 18:51:59 |
| User opened query 'Please review lab report. Lab report stated that Saliva Sample Day 28 was collected but the test results were inconclusive. ' (Site from CRA).             | (b) (4), (b) (6)            | 10 Feb 2021 21:42:54 |
| DataPoint Verified.   | (b) (4), (b) (6)            | 28 Jan 2021 19:20:39 |
| User entered 'No (N)'   | (b) (4), (b) (6)            | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 12 Aug 2021 13:23:35**

[Date of Collection](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 May 2021 09:50:50 |
| User signature succeeded.                                      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Un-verified.   | (b) (4)<br>(b) (4), (b) (6) | 12 Feb 2021 18:51:59 |
| User entered '04 Feb 2021' reason for change: Data Entry Error | (b) (4), (b) (6)            | 12 Feb 2021 18:51:59 |
| DataPoint Verified.  | (b) (4), (b) (6)            | 28 Jan 2021 19:20:39 |
| User entered empty.  | (b) (4), (b) (6)            | 22 Jan 2021 17:37:03 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:19:56 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:24 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 07 Jan 2021 21:01:30 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:19:56 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:24 |
| User entered '07 Jan 2021' | (b) (4), (b) (6)            | 07 Jan 2021 21:01:30 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 02 May 2021 07:19:56 |
| User signature succeeded.      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:24 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6)            | 07 Jan 2021 21:01:30 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 02 May 2021 07:19:56 |
| User entered 'SICKD1' | System           | 07 Jan 2021 21:01:30 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:20:10 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:59 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 07 Jan 2021 21:02:16 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:20:10 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:59 |
| User entered '07 Jan 2021' | (b) (4), (b) (6)            | 07 Jan 2021 21:02:16 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:20:10 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:59 |
| User entered '13:07'      | (b) (4), (b) (6)            | 07 Jan 2021 21:02:16 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 02 May 2021 07:20:10 |
| User entered '07 Jan 2021 13:07' | System           | 07 Jan 2021 21:02:16 |

US3712308

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

Height (xxx.x)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 02 May 2021 07:20:10 |
| User signature succeeded.   | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:59 |
| User closed query 'Data is required. Please provide.' (Site from System).             | System                      | 22 Jan 2021 17:11:14 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                      | 22 Jan 2021 17:11:14 |
| User entered '161.5' cm reason for change: Data Entry Error                           | (b) (4), (b) (6)            | 22 Jan 2021 17:11:14 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                      | 07 Jan 2021 21:02:16 |
| User entered empty.   | (b) (4), (b) (6)            | 07 Jan 2021 21:02:16 |
| DataPoint set to visible.   | System                      | 07 Jan 2021 21:01:30 |

US3712308

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

Weight (xxx.x)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 02 May 2021 07:20:10 |
| User signature succeeded.   | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:59 |
| User closed query 'Data is required. Please provide.' (Site from System).             | System                      | 22 Jan 2021 17:11:14 |
| Query 'Data is required. Please provide.' answered by data change (Site from System). | System                      | 22 Jan 2021 17:11:14 |
| User entered '89.1' kg reason for change: Data Entry Error                            | (b) (4), (b) (6)            | 22 Jan 2021 17:11:14 |
| User opened query 'Data is required. Please provide.' (Site from System).             | System                      | 07 Jan 2021 21:02:16 |
| User entered empty.   | (b) (4), (b) (6)            | 07 Jan 2021 21:02:16 |
| DataPoint set to visible.   | System                      | 07 Jan 2021 21:01:30 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:20:10 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:59 |
| User entered '37.2' C     | (b) (4), (b) (6)            | 07 Jan 2021 21:02:16 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:20:10 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:59 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6)            | 07 Jan 2021 21:02:16 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:20:10 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:59 |
| User entered empty.       | (b) (4), (b) (6)            | 07 Jan 2021 21:02:16 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:20:10 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:59 |
| User entered '89'         | (b) (4), (b) (6)            | 07 Jan 2021 21:02:16 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 02 May 2021 07:20:10 |
| User entered 'bpm' | System           | 07 Jan 2021 21:02:16 |

US3712308

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:20:10 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:59 |
| User entered '16'         | (b) (4), (b) (6)            | 07 Jan 2021 21:02:16 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 02 May 2021 07:20:10 |
| User entered 'breaths/min' | System           | 07 Jan 2021 21:02:16 |

US3712308

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:20:10 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:59 |
| User entered '141'        | (b) (4), (b) (6)            | 07 Jan 2021 21:02:16 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 07:20:10 |
| User entered 'mmHg' | System           | 07 Jan 2021 21:02:16 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:20:10 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:18:59 |
| User entered '99'         | (b) (4), (b) (6)            | 07 Jan 2021 21:02:16 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 07:20:10 |
| User entered 'mmHg' | System           | 07 Jan 2021 21:02:16 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:20:10 |
|                   |                  |                      |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:20:10 |
|                   |                  |                      |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:23:35**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:20:23 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:13 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 07 Jan 2021 21:02:40 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:23:35**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:20:23 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:13 |
| User entered '07 Jan 2021' | (b) (4), (b) (6)            | 07 Jan 2021 21:02:40 |

US3712308

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:23:35

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:20:32 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:22 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 07 Jan 2021 21:02:47 |

**US3712308**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 12 Aug 2021 13:23:35**

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:20:32 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:20:22 |
| User entered '07 Jan 2021' | (b) (4), (b) (6)            | 07 Jan 2021 21:02:47 |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:20:44 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:36:44 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 10 Feb 2021 21:27:34 |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:20:44 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:36:44 |
| User entered '04 Feb 2021' | (b) (4), (b) (6)            | 10 Feb 2021 21:27:34 |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 02 May 2021 07:20:44 |
| User signature succeeded.      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.            | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:36:44 |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6)            | 10 Feb 2021 21:27:34 |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:35

[Folder OID](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| Data hard locked.      | (b) (4), (b) (6) | 02 May 2021 07:20:44 |
| User entered 'SICKD28' | System           | 10 Feb 2021 21:27:34 |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:21:01 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:37:43 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 10 Feb 2021 21:28:22 |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:21:01 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:37:43 |
| User entered '04 Feb 2021' | (b) (4), (b) (6)            | 10 Feb 2021 21:28:22 |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:21:01 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:37:43 |
| User entered '07:20'      | (b) (4), (b) (6)            | 10 Feb 2021 21:28:22 |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 02 May 2021 07:21:01 |
| User entered '04 Feb 2021 07:20' | System           | 10 Feb 2021 21:28:22 |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Height \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:21:01 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:37:43 |
| User entered '161.5' cm   | (b) (4), (b) (6)            | 10 Feb 2021 21:28:22 |
| DataPoint set to visible. | System                      | 10 Feb 2021 21:27:34 |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

Weight (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:21:01 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:37:43 |
| User entered '89.1' kg    | (b) (4), (b) (6)            | 10 Feb 2021 21:28:22 |
| DataPoint set to visible. | System                      | 10 Feb 2021 21:27:34 |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:21:01 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:37:43 |
| User entered '37.1' C     | (b) (4), (b) (6)            | 10 Feb 2021 21:28:22 |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:21:01 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:37:43 |
| User entered 'Oral (Oral)' | (b) (4), (b) (6)            | 10 Feb 2021 21:28:22 |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:21:01 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:37:43 |
| User entered empty.       | (b) (4), (b) (6)            | 10 Feb 2021 21:28:22 |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:21:01 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:37:43 |
| User entered '85'         | (b) (4), (b) (6)            | 10 Feb 2021 21:28:22 |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 02 May 2021 07:21:01 |
| User entered 'bpm' | System           | 10 Feb 2021 21:28:22 |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:21:01 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:37:43 |
| User entered '16'         | (b) (4), (b) (6)            | 10 Feb 2021 21:28:22 |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 02 May 2021 07:21:01 |
| User entered 'breaths/min' | System           | 10 Feb 2021 21:28:22 |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:21:01 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:37:43 |
| User entered '130'        | (b) (4), (b) (6)            | 10 Feb 2021 21:28:22 |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 07:21:01 |
| User entered 'mmHg' | System           | 10 Feb 2021 21:28:22 |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:21:01 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:37:43 |
| User entered '88'         | (b) (4), (b) (6)            | 10 Feb 2021 21:28:22 |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 02 May 2021 07:21:01 |
| User entered 'mmHg' | System           | 10 Feb 2021 21:28:22 |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:23:35**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:21:01 |
|                   |                  |                      |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:23:35

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:21:01 |
|                   |                  |                      |

**US3712308**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:23:35**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:21:14 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:38:23 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 10 Feb 2021 21:28:37 |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:35

Date of examination (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:21:14 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:38:23 |
| User entered '04 Feb 2021' | (b) (4), (b) (6)            | 10 Feb 2021 21:28:37 |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:23:35

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:21:31 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:38:43 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)            | 10 Feb 2021 21:28:48 |

US3712308

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 12 Aug 2021 13:23:35

[Date of Collection](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:21:31 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)<br>(b) (4), (b) (6) | 10 Feb 2021 21:38:43 |
| User entered '04 Feb 2021' | (b) (4), (b) (6)            | 10 Feb 2021 21:28:48 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:35

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:16:12 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:35

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '19 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:16:12 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:23:35

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:16:12 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Folder OID](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'UNBLND_DECIDE' | System           | 23 Feb 2021 14:16:12 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:35

Date of updated informed consent (*dd MMM yyyy*)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.                                      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '19 Feb 2021' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 21:36:22 |
| User entered '06 Jan 2021'                                     | (b) (4), (b) (6)            | 23 Feb 2021 14:17:31 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:23:35**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.                  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| User entered '0' WR# 5295537               | (b) (4)               | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System                | 06 Mar 2021 09:59:58 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:35

[Was the participant unblinded?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:17:31 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:23:35**

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| User entered 'AMENDMENT 6 OR LATER<br>(AMENDMENT 6 OR LATER)' WR# 5295537 | (b) (4)               | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint.                                | System                | 06 Mar 2021 09:59:58 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:35

Date of unblinding (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '19 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:17:31 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:35

[Participant randomization assignment](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.        | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Placebo (Placebo)' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:17:31 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:35

[Actual Dose 1](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.        | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Placebo (Placebo)' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:17:31 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:23:35**

[Actual Dose 2](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.        | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Placebo (Placebo)' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:17:31 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:35

[Will participant receive mRNA-1273?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:17:31 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:23:35

[Placebo Only Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '1'  | System           | 23 Feb 2021 14:17:31 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing with mRNA-1273](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'I'  | System           | 23 Feb 2021 14:17:31 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

[Height](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.                | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

[Weight](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.                | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty.       | System           | 23 Feb 2021 14:18:43 |
| DataPoint set to visible. | System           | 23 Feb 2021 14:17:31 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

[Height](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.                | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

[Weight](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.                | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:23:35**

**BMI (xxx.x)**

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty.       | System           | 23 Feb 2021 14:18:43 |
| DataPoint set to visible. | System           | 23 Feb 2021 14:17:31 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '19 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

Time of assessment (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '09:20'      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '19 Feb 2021 09:20' | System           | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '36.9' C     | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '90'         | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'bpm' | System           | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '16'         | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'breaths/min' | System           | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '126'        | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'mmHg' | System           | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '81'         | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'mmHg' | System           | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

[Height](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.                | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:23:35

[Weight](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.                | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered missing code ND - Not Done. | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:18:43 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:23:35**

**BMI (xxx.x)**

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty.       | System           | 23 Feb 2021 14:18:43 |
| DataPoint set to visible. | System           | 23 Feb 2021 14:17:31 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 23 Feb 2021 14:19:25 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:19:25 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '19 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:19:25 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '11:02'      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:19:25 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '19 Feb 2021 11:02' | System           | 23 Feb 2021 14:19:25 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '37.0' C     | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:19:25 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:19:25 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:19:25 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '84'         | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:19:25 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'bpm' | System           | 23 Feb 2021 14:19:25 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '16'         | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:19:25 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'breaths/min' | System           | 23 Feb 2021 14:19:25 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '127'        | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:19:25 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'mmHg' | System           | 23 Feb 2021 14:19:25 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '82'         | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:19:25 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'mmHg' | System           | 23 Feb 2021 14:19:25 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:35

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:19:38 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:35

Date of examination (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:19:38 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

[Was the pregnancy test performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:20:08 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

Date of test (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '19 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:20:08 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

[Test performed](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.    | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Urine (URINE)' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:20:08 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

[Result](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.          | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Negative (NEGATIVE)' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:20:08 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

Was FSH sample collected?

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.   | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User closed query 'per CDM: if FSH sample was not collected, below fields should be blank, please clarify or reconcile' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6) | 11 Mar 2021 13:16:13 |
| Query 'per CDM: if FSH sample was not collected, below fields should be blank, please clarify or reconcile' answered with 'updated' (Site from DM). | (b) (4), (b) (6)            | 10 Mar 2021 20:13:49 |
| User opened query 'per CDM: if FSH sample was not collected, below fields should be blank, please clarify or reconcile' (Site from DM).             | (b) (4), (b) (6)            | 02 Mar 2021 20:26:13 |
| User entered 'No (N)'   | (b) (4), (b) (6)            | 23 Feb 2021 14:20:08 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

[Collection date](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.                              | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty; reason for change Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 20:13:43 |
| User entered '19 Feb 2021'                             | (b) (4), (b) (6)            | 23 Feb 2021 14:20:08 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

[Collection time](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.                              | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty; reason for change Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 20:13:43 |
| User entered '10:09'                                   | (b) (4), (b) (6)            | 23 Feb 2021 14:20:08 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered empty.              | System           | 10 Mar 2021 20:13:43 |
| User entered '19 Feb 2021 10:09' | System           | 23 Feb 2021 14:20:08 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[Was study treatment given?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:20:26 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[If No, reason not given](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:20:26 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:20:26 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:23:35**

[What was the study treatment? \(Unblinded\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'mRNA-1273'  | System           | 23 Feb 2021 14:20:26 |
| DataPoint set to visible. | System           | 23 Feb 2021 14:17:31 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '19 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:20:26 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '10:32'      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:20:26 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '19 Feb 2021 10:32' | System           | 23 Feb 2021 14:20:26 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[Which arm was used to give treatment?](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.          | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:20:26 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

What was the frequency of the study treatment dosing?

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'ONCE' | System           | 23 Feb 2021 14:20:26 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'INTRAMUSCULAR' | System           | 23 Feb 2021 14:20:26 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:35

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:17:09 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:35

Collection date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '19 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:17:09 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:23:35

Collection time (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '09:25'      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:17:09 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:23:35**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '19 Feb 2021 09:25' | System           | 23 Feb 2021 14:17:09 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:23:35

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:16:44 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:23:35

Collection date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '19 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:16:44 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:23:35**

[Collection time \(00:00 - 23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '09:25'      | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:16:44 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:23:35**

[Collection Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered '19 Feb 2021 09:25' | System           | 23 Feb 2021 14:16:44 |

US3712308

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 16:44:08 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Feb 2021 14:21:20 |

**US3712308**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 16:44:08 |
| User entered 'I'  | System           | 23 Feb 2021 14:21:20 |

**US3712308**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 11:47:39 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 20:20:08 |

**US3712308**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 29 Apr 2021 11:47:39 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered '26 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 20:20:08 |

**US3712308**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 29 Apr 2021 11:47:39 |
| User signature succeeded.                  | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 20:20:08 |

**US3712308**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 11:47:39 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 20:20:08 |

**US3712308**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 29 Apr 2021 11:47:39 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 01:00:38 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 10 Mar 2021 20:20:10 |

**US3712308**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 11:47:39 |
| User entered 'I'  | System           | 10 Mar 2021 20:20:10 |

**US3712308**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[OLD29 Placebo Flag](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 29 Apr 2021 11:47:39 |
| User entered '1'          | System           | 10 Mar 2021 20:20:10 |
| DataPoint set to visible. | System           | 10 Mar 2021 20:20:10 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:33:49 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '26 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:33:49 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded.      | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:33:49 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:23:35**

[Folder OID](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered 'OLD29' | System           | 06 Apr 2021 14:33:49 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User accepted default value 'Pre-Dose (PREDOSE)' | (b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

US3712308

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '26 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '14:01'      | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered '26 Mar 2021 14:01' | System           | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '37.2' C     | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '76'         | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered 'bpm' | System           | 06 Apr 2021 14:35:40 |

US3712308

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '16'         | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered 'breaths/min' | System           | 06 Apr 2021 14:35:40 |

US3712308

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '122'        | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered 'mmHg' | System           | 06 Apr 2021 14:35:40 |

US3712308

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:23:35

Diastolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '81'         | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered 'mmHg' | System           | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User accepted default value 'Post-Dose (POSTDOSE)' | (b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

US3712308

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Date of assessment \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '26 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '15:14'      | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered '26 Mar 2021 15:14' | System           | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '37.0' C     | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '73'         | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered 'bpm' | System           | 06 Apr 2021 14:35:40 |

US3712308

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '16'         | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

US3712308

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered 'breaths/min' | System           | 06 Apr 2021 14:35:40 |

US3712308

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '127'        | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered 'mmHg' | System           | 06 Apr 2021 14:35:40 |

US3712308

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '82'         | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:40 |

US3712308

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:23:35

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered 'mmHg' | System           | 06 Apr 2021 14:35:40 |

US3712308

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:23:35

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:49 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:23:35**

**Date of examination (dd MMM yyyy)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:35:49 |

US3712308

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

[Was the pregnancy test performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:34:20 |

US3712308

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

Date of test (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '26 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:34:20 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Test performed](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded.    | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Urine (URINE)' | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:34:20 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Result](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded.          | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Negative (NEGATIVE)' | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:34:20 |

US3712308

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:23:35

[Was FSH sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:34:20 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Collection date](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:34:20 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Collection time](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:34:20 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:23:35**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered empty. | System           | 06 Apr 2021 14:34:20 |

US3712308

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[Was study treatment given?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:36:08 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:23:35**

[If No, reason not given](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:36:08 |

US3712308

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:36:08 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:23:35**

[What was the study treatment? \(Unblinded\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered 'mRNA-1273'  | System           | 06 Apr 2021 14:36:08 |
| DataPoint set to visible. | System           | 10 Mar 2021 20:20:10 |

US3712308

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '26 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:36:08 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:23:35**

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '14:44'      | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:36:08 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:23:35**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered '26 Mar 2021 14:44' | System           | 06 Apr 2021 14:36:08 |

US3712308

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[Which arm was used to give treatment?](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded.          | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:36:08 |

US3712308

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered 'ONCE' | System           | 06 Apr 2021 14:36:08 |

US3712308

Folder: OL-D29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:23:35

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered 'INTRAMUSCULAR' | System           | 06 Apr 2021 14:36:08 |

US3712308

Folder: OL-D29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 19:05:40 |
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:39:21 |

**US3712308**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 19:05:40 |
| User entered 'I'  | System           | 06 Apr 2021 14:39:21 |

**US3712308**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:39:53 |

**US3712308**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered '02 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:39:53 |

**US3712308**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                  | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:39:53 |

**US3712308**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:23:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:39:53 |

US3712308

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:23:35

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 12 Apr 2021 01:14:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 06 Apr 2021 14:39:56 |

**US3712308**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:23:35**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 06 Apr 2021 14:39:56 |

US3712308

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:23:35

[Did the participant experience any adverse events?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 03 May 2021 15:39:06 |
| User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES/MYALGIA (start date: Day 6 - 28NOV2020; end date: Day 10 - 02DEC2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).   | (b) (4), (b) (6)      | 05 Apr 2021 12:07:17 |
| Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES/MYALGIA (start date: Day 6 - 28NOV2020; end date: Day 10 - 02DEC2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updating' (Site from DM).  | (b) (4), (b) (6)      | 31 Mar 2021 16:38:27 |
| User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES/MYALGIA (start date: Day 6 - 28NOV2020; end date: Day 10 - 02DEC2020). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).   | (b) (4), (b) (6)      | 31 Mar 2021 15:44:42 |
| User signature succeeded.   | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 5; end date: Day 8), HEADACHE persist beyond Day 7 (start date: Day 1; end date: Day 12) and MUSCLE ACHES persist beyond Day 7 (start date: Day 7; end date: Day 10). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). | (b) (4), (b) (6)      | 11 Mar 2021 15:48:06 |

US3712308

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:23:35

[Did the participant experience any adverse events?](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 5; end date: Day 8), HEADACHE persist beyond Day 7 (start date: Day 1; end date: Day 12) and MUSCLE ACHES persist beyond Day 7 (start date: Day 7; end date: Day 10). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'have been added' (Site from DM). | (b) (4), (b) (6) | 10 Mar 2021 20:03:15 |
| User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 5; end date: Day 8), HEADACHE persist beyond Day 7 (start date: Day 1; end date: Day 12) and MUSCLE ACHES persist beyond Day 7 (start date: Day 7; end date: Day 10). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).                     | (b) (4), (b) (6) | 04 Feb 2021 06:08:26 |
| DataPoint Verified.   | (b) (4), (b) (6) | 28 Jan 2021 19:20:45 |
| User entered 'Yes (Y)'  | (b) (4), (b) (6) | 22 Jan 2021 17:40:38 |

US3712308

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:35

[Adverse event](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User signature succeeded.   | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.   | (b) (4)               |                      |
|   | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0. | Coder Import (b) (4)  | 22 Jan 2021 17:43:03 |
|   | (b) (4)               |                      |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 22 Jan 2021 17:43:03 |
|   | (b) (4)               |                      |
| Data point term sent to Coder   | System                | 22 Jan 2021 17:42:38 |
| User entered 'covid 19'   | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |
|   |                       |                      |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this a medically-attended AE?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               | 28 Jan 2021 19:37:45 |
|                           | (b) (4), (b) (6)      |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |
|                           |                       |                      |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

US3712308

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User closed query 'Per sponsor review: Covid-19 AE present but Is this event a confirmed diagnosis of Symptomatic Covid-19? Is marked NO, please review and reconcile or otherwise clarify' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6) | 12 Apr 2021 17:22:34 |
| Query 'Per sponsor review: Covid-19 AE present but Is this event a confirmed diagnosis of Symptomatic Covid-19? Is marked NO, please review and reconcile or otherwise clarify' answered with 'updated' (Site from DM). | (b) (4), (b) (6)            | 09 Apr 2021 11:51:58 |
| DataPoint Un-verified.  | (b) (4), (b) (6)            | 09 Apr 2021 11:51:37 |
| Signature has been broken.  | (b) (4), (b) (6)            | 09 Apr 2021 11:51:37 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | (b) (4), (b) (6)            | 09 Apr 2021 11:51:37 |
| User opened query 'Per sponsor review: Covid-19 AE present but Is this event a confirmed diagnosis of Symptomatic Covid-19? Is marked NO, please review and reconcile or otherwise clarify' (Site from DM).             | (b) (4), (b) (6)            | 08 Apr 2021 22:32:55 |
| User signature succeeded.   | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| DataPoint Verified.   | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:37:45 |
| User entered 'No (N)'   | (b) (4), (b) (6)            | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered '04 Jan 2021' | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered empty.       | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered empty.       | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[End time \(00:00-23:59\)](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered empty.       | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 17:41:38 |

US3712308

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:35

[Severity](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.  | (b) (4)               |                      |
|  | (b) (4), (b) (6)      | 10 Feb 2021 22:35:40 |
| User closed query 'Please have PI/ Sub-I confirm this severity as the subject's O2 did drop to 88% for a couple days and at 90%. Please ensure this is reviewed and updated as needed.' (Site from CRA).             | (b) (4), (b) (6)      | 10 Feb 2021 22:35:38 |
| Query 'Please have PI/ Sub-I confirm this severity as the subject's O2 did drop to 88% for a couple days and at 90%. Please ensure this is reviewed and updated as needed.' answered with 'updated' (Site from CRA). | (b) (4), (b) (6)      | 09 Feb 2021 19:29:04 |
| DataPoint Un-verified.   | (b) (4), (b) (6)      | 09 Feb 2021 19:28:38 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error   | (b) (4), (b) (6)      | 09 Feb 2021 19:28:38 |
| DataPoint Verified.  | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User opened query 'Please have PI/ Sub-I confirm this severity as the subject's O2 did drop to 88% for a couple days and at 90%. Please ensure this is reviewed and updated as needed.' (Site from CRA).             | (b) (4), (b) (6)      | 28 Jan 2021 19:29:46 |
| User entered 'Grade 1/Mild (Grade 1/Mild)'   | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Is the adverse event serious?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               | 28 Jan 2021 19:37:45 |
|                           | (b) (4), (b) (6)      |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |
|                           |                       |                      |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Death](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

US3712308

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:35

[Life threatening](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

US3712308

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:35

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered empty.       | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

US3712308

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:35

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered empty.       | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Admitted to ICU?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered empty.       | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Number of Days in ICU](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered empty.       | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Congenital anomaly or birth defect](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

US3712308

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:35

[Other medically important event](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Relationship to investigational product](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:37:45 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6)            | 22 Jan 2021 17:41:38 |

US3712308

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:23:35

[Relationship to Study Procedure](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| DataPoint Verified.                      | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:37:45 |
| User entered 'Not Related (NOT RELATED)' | (b) (4), (b) (6)            | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Action taken with investigational product](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                      | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| DataPoint Verified.                            | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 19:37:45 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4), (b) (6)            | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[None](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Concomitant Medication](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered 'I'          | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Concomitant Procedure](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Outcome](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User signature succeeded.                                  | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.  | (b) (4)               |                      |
|  | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered empty.       | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Narrative](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:37:45 |
| User entered empty.       | (b) (4), (b) (6)      | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Jan 2021 17:41:38 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:03 |
|                   |                  |                      |

US3712308

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:35

[Adverse event](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 12:19:03 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0. | Coder Import (b) (4)  | 12 Mar 2021 22:30:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | (b) (4)               | 12 Mar 2021 22:30:50 |
| Data point term sent to Coder   | System                | 12 Mar 2021 22:30:14 |
| User signature succeeded.   | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0. | (b) (4)               |                      |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 24 Feb 2021 21:04:11 |
| Data point term sent to Coder   | (b) (4)               | 24 Feb 2021 21:04:11 |
| User entered 'fatigue'  | System                | 24 Feb 2021 21:03:38 |
|   | (b) (4), (b) (6)      | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this a medically-attended AE?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '27 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:19:03 |
| User entered empty. | System           | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '30 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[End time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:19:03 |
| User entered empty. | System           | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Severity](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded.                  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Is the adverse event serious?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

US3712308

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:35

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Admitted to ICU?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

US3712308

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:35

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

US3712308

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:35

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

US3712308

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:35

[Relationship to investigational product](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:06:48 |
| User entered 'Not Related (NOT RELATED)'                             | (b) (4), (b) (6)            | 24 Feb 2021 21:03:34 |

US3712308

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:35

[Relationship to Study Procedure](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:06:48 |
| User entered 'Not Related (NOT RELATED)'                             | (b) (4), (b) (6)            | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Action taken with investigational product](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'None (NONE)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[None](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Concomitant Medication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Concomitant Procedure](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

US3712308

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:23:35

[Outcome](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded.                                 | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Recovered/Resolved<br>(RECOVERED/RESOLVED)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Narrative](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:03 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:03 |
| User entered '0'  | System           | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:03 |
| User entered '1'  | System           | 24 Feb 2021 21:03:34 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:03 |
|                   |                  |                      |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:08 |
|                   |                  |                      |

US3712308

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:35

[Adverse event](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 28 Apr 2021 12:19:08 |
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 12 Mar 2021 22:46:55 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)  | 12 Mar 2021 22:46:55 |
| Data point term sent to Coder  | System                           | 12 Mar 2021 22:30:14 |
| User signature succeeded.  | William Smith (b) (4)<br>(b) (4) | 12 Mar 2021 22:30:14 |
| User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 24 Feb 2021 21:05:01 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)  | 24 Feb 2021 21:05:01 |
| Data point term sent to Coder  | System                           | 24 Feb 2021 21:04:40 |
| User entered 'headache'  | (b) (4), (b) (6)                 | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this a medically-attended AE?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '23 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Start time \(00:00-23:59\)](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 12:19:08 |
| User signature succeeded.   | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4)               | 24 Feb 2021 21:06:30 |
| User entered '18:00' reason for change: Data Entry Error                  | (b) (4), (b) (6)      | 24 Feb 2021 21:06:30 |
| User opened query 'Data is required. Please provide.' (Site from System). | System                | 24 Feb 2021 21:04:09 |
| User entered empty.   | (b) (4), (b) (6)      | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[AE start date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:19:08 |
| User entered '23 Oct 2020 18:00' | System           | 24 Feb 2021 21:06:30 |
| User entered empty.              | System           | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '03 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

US3712308

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:35

End time (00:00-23:59)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 12:19:08 |
| User signature succeeded.   | William Smith (b) (4) | 12 Mar 2021 22:30:14 |
| User closed query 'Data is required. Please provide.' (Site from System). | (b) (4)               | 24 Feb 2021 21:06:30 |
| User entered '08:00' reason for change: Data Entry Error                  | (b) (4), (b) (6)      | 24 Feb 2021 21:06:30 |
| User opened query 'Data is required. Please provide.' (Site from System). | System                | 24 Feb 2021 21:04:09 |
| User entered empty.   | (b) (4), (b) (6)      | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[AE End Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 12:19:08 |
| User entered '03 Nov 2020 08:00' | System           | 24 Feb 2021 21:06:30 |
| User entered empty.              | System           | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Severity](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded.                  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Is the adverse event serious?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

US3712308

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:35

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

US3712308

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:35

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Admitted to ICU?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

US3712308

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:23:35

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Relationship to investigational product](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:06:39 |
| User entered 'Not Related (NOT RELATED)'                             | (b) (4), (b) (6)            | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Relationship to Study Procedure](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:06:39 |
| User entered 'Not Related (NOT RELATED)'                             | (b) (4), (b) (6)            | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Action taken with investigational product](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'None (NONE)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[None](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Concomitant Medication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Concomitant Procedure](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Outcome](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded.                                 | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Recovered/Resolved<br>(RECOVERED/RESOLVED)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Narrative](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:08 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:08 |
| User entered '0'  | System           | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:08 |
| User entered '1'  | System           | 24 Feb 2021 21:04:09 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:08 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:15 |
|                   |                  |                      |

US3712308

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:35

[Adverse event](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 28 Apr 2021 12:19:15 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 12 Mar 2021 22:30:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)  | 12 Mar 2021 22:30:53 |
| Data point term sent to Coder   | System                           | 12 Mar 2021 22:30:14 |
| User signature succeeded.   | William Smith (b) (4)<br>(b) (4) | 12 Mar 2021 22:30:14 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 24 Feb 2021 21:06:11 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)  | 24 Feb 2021 21:06:11 |
| Data point term sent to Coder   | System                           | 24 Feb 2021 21:05:43 |
| User entered 'muscle aches'   | (b) (4), (b) (6)                 | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this a medically-attended AE?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '29 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:19:15 |
| User entered empty. | System           | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '01 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[End time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:19:15 |
| User entered empty. | System           | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Severity](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded.                  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Is the adverse event serious?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

US3712308

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:35

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

US3712308

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:35

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Admitted to ICU?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

US3712308

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:23:35

[Relationship to investigational product](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded.        | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Related (RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Relationship to Study Procedure](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded.        | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Related (RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Action taken with investigational product](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded.  | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'None (NONE)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[None](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Concomitant Medication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Concomitant Procedure](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Outcome](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded.                                 | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered 'Recovered/Resolved<br>(RECOVERED/RESOLVED)' | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Narrative](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:15 |
| User signature succeeded. | William Smith (b) (4)       | 12 Mar 2021 22:30:14 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:15 |
| User entered '0'  | System           | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:15 |
| User entered 'I'  | System           | 24 Feb 2021 21:05:27 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:15 |
|                   |                  |                      |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[AEID](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:21 |
|                   |                  |                      |

US3712308

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:23:35

[Adverse event](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 28 Apr 2021 12:19:21 |
| User signature succeeded.   | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0. | Coder Import (b) (4)  | 31 Mar 2021 16:42:10 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 31 Mar 2021 16:42:10 |
| Data point term sent to Coder   | System                | 31 Mar 2021 16:40:42 |
| User entered 'muscle aches '  | (b) (4), (b) (6)      | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this a medically-attended AE?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '28 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[AE start date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:19:21 |
| User entered empty. | System           | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

US3712308

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:23:35

If not Ongoing, end date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '02 Dec 2020' | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[End time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[AE End Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 12:19:21 |
| User entered empty. | System           | 31 Mar 2021 16:40:25 |

US3712308

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:23:35

[Severity](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded.                  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

US3712308

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:23:35

[Is the adverse event serious?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

US3712308

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:23:35

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

US3712308

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:23:35

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

US3712308

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:23:35

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Admitted to ICU?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

US3712308

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:23:35

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

US3712308

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:23:35

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

US3712308

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:23:35

[Relationship to investigational product](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded.        | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Related (RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Relationship to Study Procedure](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded.        | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Related (RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Action taken with investigational product](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                              | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded.                      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[None](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Concomitant Medication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Concomitant Procedure](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Outcome](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded.                              | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

US3712308

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 12 Aug 2021 13:23:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Narrative](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 12:19:21 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:21 |
| User entered '0'  | System           | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:21 |
| User entered '0'  | System           | 31 Mar 2021 16:40:25 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 12:19:21 |
|                   |                  |                      |

US3712308

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:35

[Adverse event](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | William Smith (b) (4)           | 18 Apr 2021 23:32:09 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Joint inflammation - version MedDRA\23.0. | (b) (4)<br>Coder Import (b) (4) | 16 Apr 2021 16:35:00 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4)            | 16 Apr 2021 16:35:00 |
| Data point term sent to Coder   | (b) (4)                         | 16 Apr 2021 15:02:31 |
| User entered 'si joint inflammation'  | System<br>(b) (4), (b) (6)      | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this a medically-attended AE?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

US3712308

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

US3712308

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:35

Start date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered '23 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

US3712308

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:35

If not Ongoing, end date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[End time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Severity](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                  | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Is the adverse event serious?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

US3712308

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:35

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

US3712308

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:35

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

US3712308

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:35

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Admitted to ICU?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

US3712308

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:35

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

US3712308

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:35

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Relationship to investigational product](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Relationship to Study Procedure](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Action taken with investigational product](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                      | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[None](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

US3712308

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:35

[Concomitant Medication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Concomitant Procedure](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Outcome](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

US3712308

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 12 Aug 2021 13:23:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Narrative](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 16 Apr 2021 15:01:35 |

**US3712308**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 16 Apr 2021 15:01:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:23:35

Were any prior/concomitant medications and/or vaccinations taken?

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 May 2021 15:39:06 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).                  | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 16:16:56 |
| Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'data updated' (Site from DM). | (b) (4), (b) (6)            | 26 Mar 2021 19:29:04 |
| User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).                  | (b) (4), (b) (6)            | 23 Mar 2021 12:54:22 |
| User entered 'Yes (Y)'   | (b) (4), (b) (6)            | 26 Oct 2020 15:16:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:35

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | William Smith (b) (4)           | 05 Apr 2021 00:44:24 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 26 Oct 2020 15:37:07 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 15:37:07 |
| Data point term sent to Coder   | System                          | 26 Oct 2020 15:17:45 |
| User entered 'nuva ring'  | (b) (4), (b) (6)                | 26 Oct 2020 15:17:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:35

[Prophylaxis](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6) | 14 Jan 2021 18:34:17 |
| Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM). | (b) (4), (b) (6)            | 14 Jan 2021 13:05:46 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | (b) (4), (b) (6)            | 14 Jan 2021 13:05:33 |
| User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).             | (b) (4), (b) (6)            | 23 Dec 2020 18:01:31 |
| User entered 'No (N)'   | (b) (4), (b) (6)            | 26 Oct 2020 15:17:07 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Indication](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded.    | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'birth control' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:35

[Dose per administration](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| Signature has been broken.   | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:03:58 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '120/15' reason for change: Data Entry Error  | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:25 |
| User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.120/0.015).' (Site from DM).             | (b) (4), (b) (6)            | 20 Jan 2021 09:55:31 |
| Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.120/0.015).' answered with 'updated' (Site from DM). | (b) (4), (b) (6)            | 14 Jan 2021 13:06:38 |
| User entered '0.120/0.015' reason for change: Data Entry Error   | (b) (4), (b) (6)            | 14 Jan 2021 13:06:32 |
| User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.120/0.015).' (Site from DM).             | (b) (4), (b) (6)            | 23 Dec 2020 18:01:53 |
| User entered '120'   | (b) (4), (b) (6)            | 26 Oct 2020 15:17:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| 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.<br>' (Site from DM).                     | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 02:38:33 |
| 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.<br>' answered with 'mcg is correct ' (Site from DM). | (b) (4), (b) (6)            | 15 Mar 2021 14:49:34 |
| 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.<br>' (Site from DM).                     | (b) (4), (b) (6)            | 11 Mar 2021 06:21:33 |
| User entered 'ug (ug)'   | (b) (4), (b) (6)            | 26 Oct 2020 15:17:07 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:35**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:07 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Frequency](#)

| Audit                           | User                        | Time (GMT)           |
|---------------------------------|-----------------------------|----------------------|
| User signature succeeded.       | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'every month (QM)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:35

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:07 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Route of administration](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Vaginal (VAGINAL)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:07 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:35**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:35

Start date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'un UNK 2000' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:35

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:23:35

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:07 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:35**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:07 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:07 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:17:07 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:17:07 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '802 (802)' | System | 26 Oct 2020 15:17:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:35

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)           | 05 Apr 2021 00:44:24 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 26 Oct 2020 15:37:07 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 15:37:07 |
| Data point term sent to Coder  | System                          | 26 Oct 2020 15:17:45 |
| User entered 'levothyroxine'   | (b) (4), (b) (6)                | 26 Oct 2020 15:17:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:35

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:35

[Indication](#)

| Audit                         | User                        | Time (GMT)           |
|-------------------------------|-----------------------------|----------------------|
| User signature succeeded.     | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'hypothyroidism' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:35

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '125'        | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'ug (ug)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:35

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:35

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:35**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:35

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:35

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'un UNK 2010' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:35

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:35

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:35

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:23:35

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:35 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:17:35 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:17:35 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Oct 2020 15:17:35 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:35

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)           | 05 Apr 2021 00:44:24 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM HYDROBROMIDE, PRODUCTSYNONYM: CELEXA [CITALOPRAM HYDROBROMIDE] - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 26 Oct 2020 15:39:41 |
| 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) | 26 Oct 2020 15:39:41 |
| Data point term sent to Coder  | System                          | 26 Oct 2020 15:18:46 |
| User entered 'celexa'  | (b) (4), (b) (6)                | 26 Oct 2020 15:17:58 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:35

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:58 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:35

[Indication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'anxiety'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:58 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:35

[Dose per administration](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                | 26 Oct 2020 15:18:10 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 26 Oct 2020 15:18:10 |
| User entered '40' reason for change: Data Entry Error                                  | (b) (4), (b) (6)      | 26 Oct 2020 15:18:10 |
|  |                       |                      |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 26 Oct 2020 15:17:58 |
| User entered empty.  | (b) (4), (b) (6)      | 26 Oct 2020 15:17:58 |
|  |                       |                      |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:58 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:35

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:58 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:35

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:58 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:35**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:58 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:58 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:35**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:58 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:35

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'un UNK 2012' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:58 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:58 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:58 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:23:35

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:58 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:17:58 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:17:58 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:17:58 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Oct 2020 15:17:58 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:35

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)           | 05 Apr 2021 00:44:24 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 26 Oct 2020 15:40:51 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 15:40:51 |
| Data point term sent to Coder  | System                          | 26 Oct 2020 15:19:49 |
| User entered 'wellbutrin'  | (b) (4), (b) (6)                | 26 Oct 2020 15:19:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:35

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:35

[Indication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'anxiety'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '150'        | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:35**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:35

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:35

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:35**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:35

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'un UNK 2012' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:23:35

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:35**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:19:33 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:19:33 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:19:33 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Oct 2020 15:19:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:35

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)           | 05 Apr 2021 00:44:24 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 26 Oct 2020 15:43:55 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)            | 26 Oct 2020 15:43:55 |
| Data point term sent to Coder  | System                          | 26 Oct 2020 15:20:49 |
| User entered 'zyrtec'  | (b) (4), (b) (6)                | 26 Oct 2020 15:20:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:35

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:35

[Indication](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| User signature succeeded.         | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'seasonal allergies' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '10'         | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| User entered 'mg (mg)'    | (b) (4), (b) (6)      | 26 Oct 2020 15:20:04 |
|                           |                       |                      |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:35**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:35

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:35

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:35

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:04 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:35**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:35

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'un UNK 2008' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:23:35

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:35**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:20:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:20:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Oct 2020 15:20:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:35

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | William Smith (b) (4)           | 05 Apr 2021 00:44:24 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 26 Oct 2020 15:43:17 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)            | 26 Oct 2020 15:43:17 |
| Data point term sent to Coder   | System                          | 26 Oct 2020 15:20:51 |
| User entered 'singulair'  | (b) (4), (b) (6)                | 26 Oct 2020 15:20:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:35

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:35

[Indication](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| User signature succeeded.         | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'seasonal allergies' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:35

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '10'         | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:23:35**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:35

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:35

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:35

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:23:35**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:35

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'un UNK 2016' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:35

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:35

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:35

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:23:35

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:33 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:20:33 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:20:33 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Oct 2020 15:20:33 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:35

[Name of Medication](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | William Smith (b) (4)           | 05 Apr 2021 00:44:24 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 26 Oct 2020 15:45:33 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 15:45:33 |
| Data point term sent to Coder   | System                          | 26 Oct 2020 15:21:54 |
| User entered 'omeprazole'   | (b) (4), (b) (6)                | 26 Oct 2020 15:20:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:35

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:35

[Indication](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'acid reflux' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:35**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '40'         | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:35

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:35

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:35

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:35

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:35**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:35

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'un UNK 2008' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:35

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:23:35

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:20:56 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:20:56 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Oct 2020 15:20:56 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 26 Oct 2020 15:20:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:35

[Name of Medication](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| User signature succeeded.   | William Smith (b) (4)                      | 05 Apr 2021 00:44:24 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 26 Oct 2020 15:45:34 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)            | 26 Oct 2020 15:45:34 |
| Data point term sent to Coder   | System                                     | 26 Oct 2020 15:21:54 |
| User entered 'phentermine'  | (b) (4), (b) (6)                           | 26 Oct 2020 15:21:25 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:35

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:35

[Indication](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'weight loss' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:35

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '37.5'       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:35**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:35

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'as needed (PRN)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:35**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:35**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:35**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:35

Start date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'un UNK 2019' | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:35

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:35

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:23:35

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 26 Oct 2020 15:21:25 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 15:21:25 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 15:21:25 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Oct 2020 15:21:25 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:35

[Name of Medication](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| User signature succeeded.   | William Smith (b) (4)                      | 05 Apr 2021 00:44:24 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: AGENTS<br>ACTING ON THE RENIN-ANGIOTENSIN<br>SYSTEM, ATC: ANGIOTENSIN II RECEPTOR<br>BLOCKERS (ARBS), COMBINATIONS, ATC:<br>ANGIOTENSIN II RECEPTOR BLOCKERS<br>(ARBS) AND DIURETICS, PRODUCT:<br>HYDROCHLOROTHIAZIDE;VALSARTAN,<br>PRODUCTSYNONYM: VALSARTAN HCTZ -<br>version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 22 Jan 2021 17:25:17 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)            | 22 Jan 2021 17:25:17 |
| Data point term sent to Coder   | System                                     | 22 Jan 2021 17:08:57 |
| User entered 'valsartan hctz'   | (b) (4), (b) (6)                           | 22 Jan 2021 17:08:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:35**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:35

[Indication](#)

| Audit                       | User                        | Time (GMT)           |
|-----------------------------|-----------------------------|----------------------|
| User signature succeeded.   | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'hypertension' | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:35

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '160/12.5'   | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:35**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:35

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:35

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:35**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:35**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:35

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'un UNK 2017' | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 12 Aug 2021 13:23:35

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:08:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Jan 2021 17:08:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Jan 2021 17:08:04 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 22 Jan 2021 17:08:04 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:35

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)           | 05 Apr 2021 00:44:24 |
| DataPoint Verified.  | (b) (4)                         |                      |
|  | (b) (4), (b) (6)                | 28 Jan 2021 19:38:20 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN,<br>PRODUCTSYNONYM: ADVIL [IBUPROFEN] -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4) | 22 Jan 2021 17:40:02 |
| 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) | 22 Jan 2021 17:40:02 |
| Data point term sent to Coder  | System                          | 22 Jan 2021 17:39:37 |
| User entered 'ADVIL'   | (b) (4), (b) (6)                | 22 Jan 2021 17:38:38 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:35

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:35**

[Indication](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered 'covid 19'   | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:35**

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered '400'        | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered 'mg (mg)'    | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:35

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered empty.       | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:35

[Frequency](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded.      | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.            | (b) (4)               |                      |
|                                | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered 'as needed (PRN)' | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:35**

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered empty.       | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:35**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered 'Oral (ORAL)' | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:35

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered empty.       | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:35

Start date (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.        | (b) (4)               |                      |
|                            | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered '04 Jan 2021' | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:35**

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered '0'          | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:35

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered empty.       | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 12 Aug 2021 13:23:35

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| DataPoint Verified.       | (b) (4)               |                      |
|                           | (b) (4), (b) (6)      | 28 Jan 2021 19:38:20 |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 22 Jan 2021 17:38:38 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 17:38:38 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 17:38:38 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Jan 2021 17:38:38 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:23:35

[Name of Medication](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 02 May 2021 07:09:29 |
| User signature succeeded.   | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 22 Jan 2021 17:41:03 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)  | 22 Jan 2021 17:41:03 |
| Data point term sent to Coder   | System                | 22 Jan 2021 17:40:38 |
| User entered 'omeprazole'   | (b) (4), (b) (6)      | 22 Jan 2021 17:39:46 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:23:35

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:23:35

[Indication](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'acid reflux' | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:23:35

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '40'         | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:23:35

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:23:35

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded.      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:23:35

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:23:35**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:23:35

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:23:35

Start date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'un UNK 2008' | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:23:35

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:23:35

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '13 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 12 Aug 2021 13:23:35

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 02 May 2021 07:09:29 |
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:39:46 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:09:29 |
| User entered '1'  | System           | 22 Jan 2021 17:39:46 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 02 May 2021 07:09:29 |
| User entered '1'  | System           | 22 Jan 2021 17:39:46 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 02 May 2021 07:09:29 |
| User entered '804 (804)' | System           | 22 Jan 2021 17:39:46 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:23:35

Name of Medication

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User signature succeeded.   | William Smith (b) (4)           | 05 Apr 2021 00:44:24 |
| User closed query 'Per DM CLR: Con Med NEXIUM was added/changed on 15 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6)     | 26 Mar 2021 02:40:25 |
| Query 'Per DM CLR: Con Med NEXIUM was added/changed on 15 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'has not worsened, just started new medication ' (Site from DM). | (b) (4), (b) (6)                | 15 Mar 2021 14:50:24 |
| User opened query 'Per DM CLR: Con Med NEXIUM was added/changed on 15 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).  | (b) (4), (b) (6)                | 09 Mar 2021 03:04:21 |
| User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.                                    | Coder Import (b) (4)<br>(b) (4) | 22 Jan 2021 17:41:03 |
| 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 Jan 2021 17:41:03 |
| Data point term sent to Coder   | System                          | 22 Jan 2021 17:40:37 |
| User entered 'nexium'   | (b) (4), (b) (6)                | 22 Jan 2021 17:40:07 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

3204 of 3258

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:23:35

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:23:35

[Indication](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'acid reflux' | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:23:35

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '40'         | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:23:35

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:23:35

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:23:35

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:23:35**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:23:35**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:23:35

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '15 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:23:35

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:23:35

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 12 Aug 2021 13:23:35

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:40:07 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Jan 2021 17:40:07 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Jan 2021 17:40:07 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 22 Jan 2021 17:40:07 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:23:35

[Name of Medication](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|   |                       |                      |
| User signature succeeded.   | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|   | (b) (4)               |                      |
| User coded data point as ATC:<br>DERMATOLOGICALS, ATC: OTHER<br>DERMATOLOGICAL PREPARATIONS, ATC:<br>OTHER DERMATOLOGICAL PREPARATIONS,<br>ATC: OTHER DERMATOLOGICALS, PRODUCT:<br>BOTULINUM TOXIN TYPE A,<br>PRODUCTSYNONYM: BOTOX - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 26 Mar 2021 19:29:28 |
|   | (b) (4)               |                      |
| User coded data point as Term Coded data point by   | Coder Import (b) (4)  | 26 Mar 2021 19:29:28 |
| User: Coder System - version<br>WHODrug-Global-B3\\202003.  | (b) (4)               |                      |
| Data point term sent to Coder   | System                | 26 Mar 2021 19:29:07 |
| User entered 'Botox'  | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|   |                       |                      |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:23:35

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|                           |                       |                      |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:23:35**

[Indication](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|                                  |                       |                      |
| User signature succeeded.        | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                                  | (b) (4)               |                      |
| User entered 'elective cosmetic' | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|                                  |                       |                      |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:23:35**

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| User entered '20'         | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|                           |                       |                      |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit                        | User                  | Time (GMT)           |
|------------------------------|-----------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|                              |                       |                      |
| User signature succeeded.    | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                              | (b) (4)               |                      |
| User entered 'Other (OTHER)' | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|                              |                       |                      |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:23:35

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| User entered 'units'      | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|                           |                       |                      |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:23:35**

[Frequency](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
| User entered 'once (ONCE)' | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:23:35

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| User entered empty.       | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|                           |                       |                      |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:23:35**

[Route of administration](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|  |                       |                      |
| User signature succeeded.                  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|  | (b) (4)               |                      |
| User entered 'Subcutaneous (SUBCUTANEOUS)' | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|  |                       |                      |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:23:35

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| User entered empty.       | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|                           |                       |                      |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:23:35

Start date (dd MMM yyyy)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'UN Oct 2020' | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|                            |                       |                      |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:23:35

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| User entered '0'          | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|                           |                       |                      |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|                           |                       |                      |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:23:35

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|                            |                       |                      |
| User signature succeeded.  | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                            | (b) (4)               |                      |
| User entered 'UN Oct 2020' | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|                            |                       |                      |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:23:35

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 May 2021 05:03:46 |
|                           |                       |                      |
| User signature succeeded. | William Smith (b) (4) | 05 Apr 2021 00:44:24 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 26 Mar 2021 19:28:56 |
|                           |                       |                      |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 May 2021 05:03:46 |
|                     |                  |                      |
| User entered empty. | System           | 26 Mar 2021 19:28:56 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 May 2021 05:03:46 |
|                     |                  |                      |
| User entered empty. | System           | 26 Mar 2021 19:28:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 12 Aug 2021 13:23:35

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 May 2021 05:03:46 |
|                     |                  |                      |
| User entered empty. | System           | 26 Mar 2021 19:28:56 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:23:35

[Name of Medication](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: OXICAMS, PRODUCT:<br>MELOXICAM, PRODUCTSYNONYM: MOBIC -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)  | 20 Apr 2021 13:17:54 |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)  | 20 Apr 2021 13:17:54 |
| User signature succeeded.  | William Smith (b) (4)<br>(b) (4) | 18 Apr 2021 23:32:09 |
| Data point term sent to Coder  | System                           | 16 Apr 2021 15:06:45 |
| User entered 'mobic'   | (b) (4), (b) (6)                 | 16 Apr 2021 15:05:47 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:23:35

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:23:35

[Indication](#)

| Audit                                | User                        | Time (GMT)           |
|--------------------------------------|-----------------------------|----------------------|
| User signature succeeded.            | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'si joint inflammation' | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:23:35

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered '15'         | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:23:35

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:23:35

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:23:35

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:23:35

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:23:35**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:23:35**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:23:35

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered '23 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:23:35

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:23:35**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

US3712308

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 12 Aug 2021 13:23:35

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

US3712308

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:23:35**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 18 Apr 2021 23:32:09 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 15:05:47 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:23:35**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 16 Apr 2021 15:05:47 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 16 Apr 2021 15:05:47 |

**US3712308**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 12 Aug 2021 13:23:35**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 16 Apr 2021 15:05:47 |

US3712308

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 12 Aug 2021 13:23:35**

[Were any concomitant procedures performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | William Smith (b) (4)       | 05 Apr 2021 00:44:24 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 05 Feb 2021 17:22:55 |