

US3312465 (Prod: Johnson County Clin-Trials)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:03:25

All time stamps listed in this document are displayed in GMT

US3312465

Form: Participant Creation

Data signed: (b) (4) 06 Apr 2021 02:47:02

Generated On: 09 Jun 2021 17:03:25

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Participant ID

US3312465

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

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US3312465

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

|   |  |
|---|--|
| Date of Birth (MMM yyyy)                  | (b) (6) 2002   |
| Age                                       | 18   |
| Age Units                                 | YEARS  |
| Age (Derived)                             | 18   |
| Sex                                       | Female <input type="radio"/><br>Male <input checked="" type="radio"/>  |
| Ethnicity                                 | Hispanic or Latino <input type="radio"/><br>Not Hispanic or Latino <input checked="" type="radio"/><br>Not Reported <input type="radio"/><br>Unknown <input type="radio"/> |
| Race (Check All That Apply)               |  |
| White                                     | True   |
| Black                                     | False  |
| Asian                                     | False  |
| American Indian or Alaska Native          | False  |
| Native Hawaiian or other Pacific Islander | False  |
| Other                                     | False  |
| If race is Other, specify _____           |  |
| Unknown                                   | False  |
| Not reported                              | False  |

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 22:50:13

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 22:50:13

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Apr 2021 19:46:45

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|   |  |
|---|--|
| Condition   | ANXIETY  |
| Start date (dd MMM yyyy)                          | UN UNK 2016  |
| 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 2016   |
| Start Year (derived)                              | 2016   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Apr 2021 19:46:45

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|   |  |
|---|--|
| Condition   | ASTHMA   |
| Start date (dd MMM yyyy)                          | UN UNK 2018  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) |  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2018   |
| Start Year (derived)                              | 2018   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Apr 2021 19:46:45

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|   |  |
|---|--|
| Condition   | BRONCHITIS   |
| Start date (dd MMM yyyy)                          | UN UNK 2018  |
| 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 2018  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2018   |
| Start Year (derived)                              | 2018   |
| Stop Month and Year (derived)                     | JAN 2018   |
| Stop Year (derived)                               | 2018   |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Apr 2021 19:46:45

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|   |  |
|---|--|
| Condition   | RIGHT SECOND FINGER<br>BLISTER                                   |
| Start date (dd MMM yyyy)                                | 31 AUG 2020  |
| 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)                          | AUG 2020   |
| Start Year (derived)                                    | 2020   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Apr 2021 19:46:45

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Apr 2021 19:46:45

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|   |  |
|---|--|
| Condition   | ATTENTION DEFICIT DISORDER                                       |
| 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) 15 Apr 2021 19:46:45

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|   |  |
|---|--|
| Condition   | DEPRESSION   |
| Start date (dd MMM yyyy)                          | UN UNK 2016  |
| 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 2016   |
| Start Year (derived)                              | 2016   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Apr 2021 19:46:45

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|   |  |
|---|--|
| Condition   | SOCIAL ANXIETY DISORDER  |
| Start date (dd MMM yyyy)                                | UN UNK 2016  |
| 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 2016   |
| Start Year (derived)                                    | 2016   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Apr 2021 19:46:45

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|   |  |
|---|--|
| Condition   | PANIC ATTACKS  |
| Start date (dd MMM yyyy)                          | UN UNK 2016  |
| 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 2016   |
| Start Year (derived)                              | 2016   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Apr 2021 19:46:45

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|   |  |
|---|--|
| Condition   | SUICIDE ATTEMPT (X4)   |
| Start date (dd MMM yyyy)                          | UN UNK 2016  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2020  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2016   |
| Start Year (derived)                              | 2016   |
| Stop Month and Year (derived)                     | JAN 2020   |
| Stop Year (derived)                               | 2020   |

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Apr 2021 19:46:45

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|   |  |
|---|--|
| Condition   | ALCOHOL USE DISORDER   |
| Start date (dd MMM yyyy)                                | UN UNK 2016  |
| 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 2016   |
| Start Year (derived)                                    | 2016   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Apr 2021 19:46:45

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|   |  |
|---|--|
| Condition   | CANNIBIS USE DISORDER  |
| Start date (dd MMM yyyy)                          | UN UNK 2016  |
| 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 2016   |
| Start Year (derived)                              | 2016   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Apr 2021 19:46:45

Generated On: 09 Jun 2021 17:03:25

|   |  |
|---|--|
| Condition   | BENZODIAZEPINEABUSE  |
| Start date (dd MMM yyyy)                          | UN UNK 2016  |
| 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 2016   |
| Start Year (derived)                              | 2016   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

|   |                                       |
|---|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|   | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 02 SEP 2020                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 14:27 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 02 SEP 2020 14:27                     |
| Height ( <i>xxx.x</i> )                   | 74.0 in                               |
| Weight ( <i>xxx.x</i> )                   | 252.8 lb                              |
| BMI ( <i>xxx.x</i> )                      | 32.52547 kg/m <sup>2</sup>            |
| BMI units                                 | KG/M2                                 |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                         |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|   | Axillary <input type="radio"/>        |
|   | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                         |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                         |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                         |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                         |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 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: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:50:13

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

---

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 22:50:13

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

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

What was the participant's randomization number? 111088

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) 15 Feb 2021 22:50:13

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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

|                                     |  |
|-------------------------------------|--|
| 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)    | 02 SEP 2020  |
| Time of assessment (00:00-23:59)    | 14:27 (24 HR)  |
| Vital Signs Date and Time (derived) | 02 SEP 2020 14:27  |
| Temperature (xxx.x)                 | 98.1 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 62 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 137 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 82 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

|                                     |  |
|-------------------------------------|--|
| 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)    | 02 SEP 2020  |
| Time of assessment (00:00-23:59)    | 16:00 (24 HR)  |
| Vital Signs Date and Time (derived) | 02 SEP 2020 16:00  |
| Temperature (xxx.x)                 | 98.0 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 65 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 14 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 126 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 72 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:50:13

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Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:29 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 15:29

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:50:13

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Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 SEP 2020

Collection time (00:00-23:59)

14:54 (24 HR)

Collection date and time (derived)

02 SEP 2020 14:54



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:50:13

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|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 02 SEP 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 14:47                           | 02 SEP 2020 14:47                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:50:13

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Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 16:01

PC Open Date & Time

02 SEP 2020 15:49

PC Close Date & Time

02 SEP 2020 18:19

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °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        | 02 SEP 2020 21:04 |
| PC Open Date & Time  | 02 SEP 2020 19:14 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

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**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

97.8 °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

03 SEP 2020 21:59

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

04 SEP 2020 20:07

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 18:50

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 20:22

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59



US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 20:47

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 10:29

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 16:01

PC Open Date & Time

02 SEP 2020 15:49

PC Close Date & Time

02 SEP 2020 18:19

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 21:04

PC Open Date & Time

02 SEP 2020 19:14

PC Close Date & Time

03 SEP 2020 11:59

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 21:59

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 20:07

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 18:50

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 20:22

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59



US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 20:48

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**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

09 SEP 2020 10:30

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**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 ☐

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 02 SEP 2020 16:02 |
| PC Open Date & Time  | 02 SEP 2020 15:49 |
| PC Close Date & Time | 02 SEP 2020 18:19 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**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 ☐

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 02 SEP 2020 21:04 |
| PC Open Date & Time  | 02 SEP 2020 19:14 |
| PC Close Date & Time | 03 SEP 2020 11:59 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 SEP 2020 22:00 |
| PC Open Date & Time          | 03 SEP 2020 12:00 |
| PC Close Date & Time         | 04 SEP 2020 11:59 |



US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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)

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 SEP 2020 20:08 |
| PC Open Date & Time          | 04 SEP 2020 12:00 |
| PC Close Date & Time         | 05 SEP 2020 11:59 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 05 SEP 2020 18:50 |
| PC Open Date & Time          | 05 SEP 2020 12:00 |
| PC Close Date & Time         | 06 SEP 2020 11:59 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**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)

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 SEP 2020 20:23 |
| PC Open Date & Time          | 06 SEP 2020 12:00 |
| PC Close Date & Time         | 07 SEP 2020 11:59 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**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)

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 07 SEP 2020 20:48 |
| PC Open Date & Time          | 07 SEP 2020 12:00 |
| PC Close Date & Time         | 08 SEP 2020 11:59 |



US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**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)

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 09 SEP 2020 10:30 |
| PC Open Date & Time          | 08 SEP 2020 12:00 |
| PC Close Date & Time         | 09 SEP 2020 11:59 |

US3312465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312465

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:50:12

Generated On: 09 Jun 2021 17:03:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:50:10

Generated On: 09 Jun 2021 17:03:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312465

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:50:10

Generated On: 09 Jun 2021 17:03:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:50:12

Generated On: 09 Jun 2021 17:03:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312465

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:50:12

Generated On: 09 Jun 2021 17:03:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 30 SEP 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT2                                  |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

|                                     |   |
|-------------------------------------|---|
| 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)    | 30 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 12:57 (24 HR)                             |
| Vital Signs Date and Time (derived) | 30 SEP 2020 12:57                         |
| Temperature (xxx.x)                 | 98.0 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 98 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)      | 72 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

|                                     |   |
|-------------------------------------|---|
| 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)    | 30 SEP 2020                                   |
| Time of assessment (00:00-23:59)    | 14:22 (24 HR)                                 |
| Vital Signs Date and Time (derived) | 30 SEP 2020 14:22                             |
| Temperature (xxx.x)                 | 97.9 F  |
| Route of measurement                | Oral <input checked="" type="checkbox"/>      |
|                                     | Axillary <input type="checkbox"/>             |
|                                     | Other <input type="checkbox"/>                |
| If Other, specify                   |   |
| Pulse (xxx)                         | 75 beats/min                                  |
| Pulse units                         | BPM   |
| Respiratory Rate (xxx)              | 14 breaths/min                                |
| Respiratory Rate units              | BREATHS/MIN                                   |
| Systolic Blood Pressure (xxx)       | 122 mmHg                                      |
| Systolic Blood Pressure units       | MMHG  |
| Diastolic Blood Pressure (xxx)      | 67 mmHg                                       |
| Diastolic Blood Pressure units      | MMHG  |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3312465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

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) 30 SEP 2020

What was the treatment time? (00:00-23:59) 13:52 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 13:52

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

US3312465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

13:25 (24 HR)

Collection date and time (derived)

30 SEP 2020 13:25

US3312465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 30 SEP 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 13:16                           | 30 SEP 2020 13:16                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

30 SEP 2020 14:21

PC Open Date & Time

30 SEP 2020 14:12

PC Close Date & Time

30 SEP 2020 16:42

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 01 OCT 2020 07:56 |
| PC Open Date & Time  | 30 SEP 2020 17:37 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 12:30

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**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

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 18:12

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

04 OCT 2020 13:01

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**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

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

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**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

96.9 °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

06 OCT 2020 14:52

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59



US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 14:22

PC Open Date & Time

30 SEP 2020 14:12

PC Close Date & Time

30 SEP 2020 16:42

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 07:56

PC Open Date & Time

30 SEP 2020 17:37

PC Close Date & Time

01 OCT 2020 11:59

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 12:31

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**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

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 18:12

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 13:01

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**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 ☐

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

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 14:53

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59



US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**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 ☐

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 30 SEP 2020 14:21 |
| PC Open Date & Time  | 30 SEP 2020 14:12 |
| PC Close Date & Time | 30 SEP 2020 16:42 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**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 ☐

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 01 OCT 2020 07:56 |
| PC Open Date & Time  | 30 SEP 2020 17:37 |
| PC Close Date & Time | 01 OCT 2020 11:59 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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100 of 2052

EAB) (1725)

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 01 OCT 2020 12:31 |
| PC Open Date & Time          | 01 OCT 2020 12:00 |
| PC Close Date & Time         | 02 OCT 2020 11:59 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**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: 09 Jun 2021 17:03:25

Yes ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59



US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

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 ☒

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 OCT 2020 18:11 |
| PC Open Date & Time          | 03 OCT 2020 12:00 |
| PC Close Date & Time         | 04 OCT 2020 11:59 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**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 ☒

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 OCT 2020 13:02 |
| PC Open Date & Time          | 04 OCT 2020 12:00 |
| PC Close Date & Time         | 05 OCT 2020 11:59 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

Yes ☐

PC Time stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

110 of 2052

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 06 OCT 2020 14:53 |
| PC Open Date & Time          | 06 OCT 2020 12:00 |
| PC Close Date & Time         | 07 OCT 2020 11:59 |



US3312465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:50:12

Generated On: 09 Jun 2021 17:03:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312465

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:50:12

Generated On: 09 Jun 2021 17:03:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:50:12

Generated On: 09 Jun 2021 17:03:25

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3312465

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:50:12

Generated On: 09 Jun 2021 17:03:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 22:50:12

Generated On: 09 Jun 2021 17:03:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312465

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:50:12

Generated On: 09 Jun 2021 17:03:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 28 OCT 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT3                                  |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 28 OCT 2020                           |
| Time of assessment (00:00-23:59)    | 12:47 (24 HR)                         |
| Vital Signs Date and Time (derived) | 28 OCT 2020 12:47                     |
| Temperature (xxx.x)                 | 98.0 F                                |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 86 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 16 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 121 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 76 mmHg                               |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |



US3312465

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

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.*

US3312465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 28 OCT 2020                          |
| Collection time (00:00-23:59)      | 13:03 (24 HR)                        |
| Collection date and time (derived) | 28 OCT 2020 13:03                    |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 22:50:13

Generated On: 09 Jun 2021 17:03:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 18:04:10

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 22:03:40

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| TIMEPOINT   | DAY 78   |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 17 NOV 2020 02:24:51   |
| Patient Cloud Open Date & Time  | 16 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 20 NOV 2020 23:59  |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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 type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-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"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59



US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| TIMEPOINT   | DAY 89  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-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"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2020 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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   | 08 DEC 2020 12:23:31   |
| Patient Cloud Open Date & Time  | 04 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 08 DEC 2020 23:59  |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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

14 DEC 2020 15:25:33

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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 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"/>  |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 22 DEC 2020 23:59 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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

29 DEC 2020 17:38:04

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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   | 05 JAN 2021 08:21:49   |
| Patient Cloud Open Date & Time  | 01 JAN 2021 00:01  |
| Patient Cloud Close Date & Time   | 05 JAN 2021 23:59  |



US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 JAN 2021 12:16:18

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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

15 JAN 2021 11:29:24

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 05:25:37

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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

30 JAN 2021 08:26:15

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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 <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 FEB 2021 05:20:37   |
| Patient Cloud Open Date & Time  | 05 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 09 FEB 2021 23:59  |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 00:35:19

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 12:02:08

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 12:52:16

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59



US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 20:52:51

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 14:57:51

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 08:43:31

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 09:23:52

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 00:02:31

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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 checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 11 APR 2021 12:00:15   |
| Patient Cloud Open Date & Time  | 09 APR 2021 00:01  |
| Patient Cloud Close Date & Time   | 13 APR 2021 23:59  |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 13:21:19

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 00:05:28

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59



US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 12:00:44

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 250

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

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

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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°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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐  
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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 25 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 JUN 2021 23:59 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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[Patient Cloud Open Date & Time](#)

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02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUL 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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="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"/>  |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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> | 13 AUG 2021 00:01 |
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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 17 AUG 2021 23:59 |
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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐ 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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 01 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 05 OCT 2021 23:59 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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="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"/>  |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐ 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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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> | 22 OCT 2021 00:01 |
|--|-------------------|

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 26 OCT 2021 23:59 |
|---|-------------------|

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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="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"/>  |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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="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"/>  |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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26 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 DEC 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 14 DEC 2021 23:59 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 17 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 21 DEC 2021 23:59 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 DEC 2021 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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="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"/>  |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 14 JAN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 18 JAN 2022 23:59 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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[Patient Cloud Close Date & Time](#)

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25 JAN 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

28 JAN 2022 00:01

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01 FEB 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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 <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"/>  |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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04 FEB 2022 00:01

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08 FEB 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| TIMEPOINT   | DAY 530  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>  |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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11 FEB 2022 00:01

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15 FEB 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 FEB 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

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

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

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

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01 MAR 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐



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

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

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08 MAR 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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15 MAR 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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22 MAR 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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25 MAR 2022 00:01

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29 MAR 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 APR 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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08 APR 2022 00:01

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12 APR 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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°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 ☐

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

**Form: Safety Follow Up Diary**

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

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Date and time of submission

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15 APR 2022 00:01

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19 APR 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| TIMEPOINT   | DAY 607  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <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"/>  |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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="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"/>  |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 MAY 2022 00:01

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17 MAY 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| TIMEPOINT   | DAY 628   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| TIMEPOINT   | DAY 635  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>  |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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="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"/>  |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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21 JUN 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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24 JUN 2022 00:01

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28 JUN 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| TIMEPOINT   | DAY 684  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <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"/>  |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 15 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 19 JUL 2022 23:59 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| TIMEPOINT   | DAY 705  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>   |
| Chills  | <input type="checkbox"/>   |
| Cough   | <input type="checkbox"/>   |
| Shortness of breath   | <input type="checkbox"/>   |
| Difficulty breathing  | <input type="checkbox"/>   |
| Fatigue   | <input type="checkbox"/>   |
| Muscle aches  | <input type="checkbox"/>   |
| Body aches  | <input type="checkbox"/>   |
| Headache  | <input type="checkbox"/>   |
| New loss of taste   | <input type="checkbox"/>   |
| New loss of smell   | <input type="checkbox"/>   |
| Sore throat   | <input type="checkbox"/>   |
| Congestion  | <input type="checkbox"/>   |
| Runny nose  | <input type="checkbox"/>   |
| Nausea  | <input type="checkbox"/>   |
| Vomiting  | <input type="checkbox"/>   |
| Diarrhea  | <input type="checkbox"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="checkbox"/><br>Yes <input type="checkbox"/>  |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 26 AUG 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 30 AUG 2022 23:59 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>  |

**US3312465**

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**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| TIMEPOINT   | DAY 740   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 SEP 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 14 OCT 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 18 OCT 2022 23:59 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**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 ☐

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

28 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

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US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

| 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"/>   |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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04 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2022 23:59

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US3312465

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:03:25

| 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   | Yes  | 27 FEB 2021 12:52:23      |



US3312465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312465

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312465

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312465

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312465

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312465

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3312465

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3312465

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

|                           |                                      |
|---------------------------|--------------------------------------|
| 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 | VISIT4 |
|------------|--------|

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

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) \_\_\_\_\_

US3312465

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3312465

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 26 MAR 2021                          |
| Collection time (00:00-23:59)      | 10:22 (24 HR)                        |
| Collection date and time (derived) | 26 MAR 2021 10:22                    |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3312465

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

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*

**US3312465**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:03:25**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3312465

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:03:25

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



US3312465

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:03:25

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3312465

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

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 02:47:02

Generated On: 09 Jun 2021 17:03:25

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

|                          |             |
|--------------------------|-------------|
| Visit date (dd MMM yyyy) | 02 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 |
|------------|---------------|

US3312465

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

Form: Unblinding

Data signed: (b) (4) 06 Apr 2021 02:47:02

Generated On: 09 Jun 2021 17:03:25

Date of updated informed consent (dd MMM yyyy) 02 FEB 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 02 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3312465

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 02:47:02

Generated On: 09 Jun 2021 17:03:25

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 02 FEB 2021                          |
| Collection time (00:00-23:59)      | 12:27 (24 HR)                        |
| Collection date and time (derived) | 02 FEB 2021 12:27                    |

US3312465

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 06 Apr 2021 02:47:02

Generated On: 09 Jun 2021 17:03:25

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 FEB 2021

Collection time (00:00 - 23:59)

12:26

Collection Date and Time (derived)

02 FEB 2021 12:26

US3312465

Folder: Unscheduled 02 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

|  |             |
|--|-------------|
| Visit Date   | 02 FEB 2021 |
| Please check all assessments that apply for this visit |             |
| Physical Exam  | True        |
| Vital Signs  | False       |
| Immunogenicity Assessment                              | False       |
| Pregnancy Test   | False       |

US3312465

Folder: Unscheduled 02 Feb 2021

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 02:47:03

Generated On: 09 Jun 2021 17:03:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 FEB 2021

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

US3312465

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 16:03:01

Generated On: 09 Jun 2021 17:03:25

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3312465

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:59:36

Generated On: 09 Jun 2021 17:03:25

|  |  |
|--|--|
| AEID   | USA-US300-2021-MRNA-1273-P30<br>1000021  |
| Adverse event  | EXACERBATION OF<br>DEPRESSION  |
| 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)                                       | 15 DEC 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)                         | 31 MAR 2021  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | True   |
| Hospital Admission Date (dd MMM yyyy)                          | 02 MAR 2021  |
| Hospital Discharge Date (dd MMM yyyy)                          | 05 MAR 2021  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input type="radio"/><br>Unknown <input type="radio"/>   |
| PRODUCTION RELEASE (v12.003<br>EAB) (1725)                     | 336 of 2052  |

US3312465

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:59:36

Generated On: 09 Jun 2021 17:03:25

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

US3312465

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:59:36

Generated On: 09 Jun 2021 17:03:25

---

SUBJ WAS SEEN 26MAR21 FOR  
D206 FOLLOW-UP, AT WHICH  
TIME HE REPORTED HOSP  
02MAR21-05MAR21 AFTER  
SUICIDE ATTEMPT. ON  
02MAR21, SUBJ FOUND BY  
PARENT AFTER INGESTING  
UNK AMT OF  
ALPRAZOLAM&VODKA.TAKEN  
TO HOSP VIA EMS. SUBJ ADM  
TO 4 SIMILAR ATTEMPTS SINCE  
2016, ALTHOUGH NOT PREV  
REPORTED TO SITE.AT TIME OF  
INITIAL SCREEN, SUBJ WAS  
NOTED TO HAVE HX OF  
DEPRESSION SINCE 2016, TX  
WITH KLONIPIN SINCE  
APR2020. SEP2020, SUBJ  
REPORTED HE HAD BEEN  
PRESCRIBED ALPRAZOLAM IN  
APR2020 IN ADDITION TO  
KLONIPIN.DIDN'T FILL  
ALPRAZOLAM RX IN ATTEMPT  
TO CNTRL SX WITH MIN  
MEDS.ROUTINE TELEMED  
WITH PSYCHIATRIST  
RESULTED IN RENEWED  
ALPRAZOLAM RX D/T STABLE,  
BUT UNIMPROVED  
DEPRESSION.FEB2021, SUBJ  
BEGAN  
FLUOXITINE&TRAZADONE FOR  
EXAC OF DEPRESSION. AFTER  
02MAR21 SUICIDE ATTEMPT,  
SUBJ RX GABAPENTIN,INCR

US3312465

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:59:36

Generated On: 09 Jun 2021 17:03:25

---

DOSE OF TRAZADONE&INSTR  
TO DC  
KLONOPIN&ALPRAZOLAM.ME  
DS CURR MANAGED BY PCP,  
LAST SEEN 24MAR21. CURR  
ADMITS TO FEELING  
DEPRESSED BUT "BETTER  
SINCE GETTING OUT OF HOSP."  
DENIES SI. REPORTS LIVING  
WITH PARENTS&RETURNING  
TO WORK AND DAILY  
ACTIVITIES&NML ROUTINE. PE  
UNREMARKABLE.MED REC  
REVIEWED CONFIRMING HOSP  
02MAR21-05MAR21 FOR  
ALPRAZOLAM  
OVERDOSE.PRESENTED TO  
HOSP WITH HX OF TAKING  
56MG OF ALPRAZOLAM&2  
SHOTS ETOH OVER 13 HRS &  
REG SCHED KLONAZEPAM.  
(b) (6) PARENTS CALLED EMS.  
SUBJ SOMEWHAT DROWSY IN  
ER, VERY LITTLE OTHER  
SEVERE SYMPTOMS. SUBJ  
DENIED SUICIDE ATTEMPT,  
STATED OVERDOSE D/T  
CYCLING THRU FORGETTING  
HE TOOK  
ALPRAZOLAM&RETAKING IT,  
UNTIL HE REALIZED HE HAD  
TAKEN 56MG. HAS HX OF  
DEPRESSION&ANXIETY.CITED  
FINANCIAL&JOB  
STRESS&PANIC ATTACKS,LOW

US3312465

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 15:59:36

Generated On: 09 Jun 2021 17:03:25

---

ENERGY,LOW  
CONCENTRATION&LOW  
SELF-WORTH AS  
CONTRIBUTING FACTORS.UDS  
POS FOR BENZOS&MARIJUANA.  
HE ENDORSED FREQ ETOH USE.  
BLOOD ETOH REPORTED AS  
"11." HIS MOM CONCERNED  
SUBJ WAS DIVERTING MEDS.  
BENZOS DC'D DURING  
HOSP,STAFF SURPRISED AT  
LACK OF WITHDRAWAL  
SYMPT. SUBJ CURR MANAGED  
BY PCP&OUTPT PSYCH.DENIES  
SI, BACK TO NML PRE-EVENT  
ROUTINE, INCL WORK.EXAC OF  
PRE-EXISTING DEPRESSION  
RESOLVED.SUBJ BACK TO  
BASELINE.WILL CLOSE SAE.  
NOT RELATED TO IP.

---

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

---

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US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:59:36

Generated On: 09 Jun 2021 17:03:25

|  |  |
|--|--|
| AEID   | USA-US300-2021-MRNA-1273-P30<br>1000021  |
| Adverse event  | SUICIDE ATTEMPT  |
| 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)                                       | 02 MAR 2021  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         | 02 MAR 2021  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input type="radio"/><br>Grade 3/Severe <input checked="" type="radio"/><br>Grade 4 <input type="radio"/> |
| Is the adverse event serious?                                  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| AE is serious due To (check all that apply)                    |  |
| Death  | False  |
| Life threatening   | False  |
| Requires inpatient or prolongation of existing Hospitalization | True   |
| Hospital Admission Date (dd MMM yyyy)                          | 02 MAR 2021  |
| Hospital Discharge Date (dd MMM yyyy)                          | 05 MAR 2021  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>  |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:59:36

Generated On: 09 Jun 2021 17:03:25

|  |  |
|--|--|
| Number of Days in ICU  |  |
| Persistent or significant disability or incapacity                           | False  |
| Congenital anomaly or birth defect   | False  |
| Other medically important event  | False  |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/>           |
|  | Related <input type="radio"/>                          |
|  | Not Applicable <input type="radio"/>                   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/>           |
|  | Related <input type="radio"/>                          |
|  | Not Applicable <input type="radio"/>                   |
| Action taken with investigational product                                    | None <input type="radio"/>                             |
|  | Dose Delayed <input type="radio"/>                     |
|  | Investigational Product <input type="radio"/>          |
|  | Withdrawn <input type="radio"/>                        |
|  | 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"/>                            |
|  | Not Recovered/Not Resolved <input type="radio"/>       |
|  | Recovered/Resolved <input checked="" type="radio"/>    |
|  | Recovered/Resolved with Sequelae <input type="radio"/> |
|  | Recovering/Resolving <input type="radio"/>             |
|  | Unknown <input type="radio"/>                          |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |  |
| Narrative  |  |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:59:36

Generated On: 09 Jun 2021 17:03:25

---

SUBJECT WAS SEEN ON  
26MAR2021 FOR D206  
FOLLOW-UP, AT WHICH TIME  
HE REPORTED  
HOSPITALIZATION FROM  
02MAR2021 TO 05MAR2021  
FOLLOWING SUICIDE  
ATTEMPT. ON 02MAR2021,  
SUBJECT WAS FOUND BY  
PARENT AFTER INGESTING  
UNKNOWN AMOUNT OF  
ALPRAZOLAM AND VODKA,  
AND TAKEN TO LOCAL  
HOSPITAL VIA EMS. SUBJECT  
ADMITS TO FOUR SIMILAR  
SUCH ATTEMPTS SINCE 2016,  
ALTHOUGH NOT PREVIOUSLY  
REPORTED TO OUR SITE. AT  
TIME OF INITIAL SCREENING,  
SUBJECT WAS NOTED TO HAVE  
HX OF DEPRESSION SINCE 2016,  
TREATED WITH KLONIPIN  
SINCE APR2020. IN SEP2020,  
SUBJECT REPORTED THAT HE  
HAD BEEN PRESCRIBED  
ALPRAZOLAM IN APR2020 IN  
ADDITION TO KLONIPIN, BUT  
DID NOT FILL ALPRAZOLAM  
RX IN ATTEMPT TO CONTROL  
SX WITH MINIMAL  
MEDICATION. PER PATIENT,  
ROUTINE TELEMEDICINE VISIT  
WITH PSYCHIATRIST  
RESULTED IN RENEWED  
ALPRAZOLAM RX DUE TO



US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 15:59:36

Generated On: 09 Jun 2021 17:03:25

---

STABLE, BUT UNIMPROVED  
DEPRESSION. IN FEB2021,  
SUBJECT BEGAN TAKING  
FLUOXITINE AND TRAZADONE  
FOR EXACERBATION OF  
DEPRESSION. FOLLOWING  
02MAR2021 SUICIDE ATTEMPT,  
SUBJECT WAS PRESCRIBED  
GABAPENTIN AND INCREASED  
DOSE OF TRAZADONE AND  
INSTRUCTED TO DISCONTINUE  
KLONOPIN AND ALPRAZOLAM.  
MEDICATIONS CURRENTLY  
MANAGED BY PCP, LAST SEEN  
ON 24MAR2021. SUBJECT  
AWAITING FIRST  
APPOINTMENT WITH NEW  
PSYCHIATRIST REFERRED BY  
PCP. CURRENTLY ADMITS TO  
FEELING DEPRESSED BUT  
"BETTER SINCE GETTING OUT  
OF THE HOSPITAL." DENIES  
SUICIDAL IDEATION. REPORTS  
LIVING WITH HIS PARENTS  
AND RETURNING TO WORK  
AND DAILY ACTIVITIES AS PER  
NORMAL ROUTINE. PHYSICAL  
EXAM UNREMARKABLE.  
AWAITING RECORDS

---

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

---

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 15:59:36

Generated On: 09 Jun 2021 17:03:25

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 16:15:49

Generated On: 09 Jun 2021 17:03:25

Name of Medication KLONOPIN

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 16:15:49

Generated On: 09 Jun 2021 17:03:25

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | UN APR 2020              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             | 02 MAR 2021              |                                     |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | 1                        |                                     |
| Interval Dosage Unit Number (derived)              | 1                        |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input checked="" type="checkbox"/> |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           | UN UNK 2018              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input checked="" type="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) _____             |                          |                                     |
| Interval Dosage Unit Number (derived) _____        |                          |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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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)                           |                          | 30 SEP 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 02 MAR 2021                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   | _____                    |                                     |
| Interval Dosage Unit Number (derived)              | _____                    |                                     |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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Name of Medication FLUOXETINE

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION OF  
DEPRESSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify   |                          |                                     |
| Start date (dd MMM yyyy)                       | 02 FEB 2021              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 05 FEB 2021              |                                     |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               | 1                        |                                     |
| Interval Dosage Unit Number (derived)          | 1                        |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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Name of Medication TRAZADONE

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION OF  
DEPRESSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify   |                          |                                     |
| Start date (dd MMM yyyy)                       | 02 FEB 2021              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         |                          | 01 MAR 2021                         |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               | 1                        |                                     |
| Interval Dosage Unit Number (derived)          | 1                        |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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Name of Medication FLUOXETINE

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION OF  
DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Intraocular              | <input type="checkbox"/>            |
|  | Intramuscular            | <input type="checkbox"/>            |
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify   |                          |                                     |
| Start date (dd MMM yyyy)                       | 06 FEB 2021              |                                     |
| Start date completely unknown                  | False                    |                                     |
| Ongoing?                                       | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)         | 05 MAR 2021              |                                     |
| Was this medication taken for solicited event? | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)               | 1                        |                                     |
| Interval Dosage Unit Number (derived)          | 1                        |                                     |
| Interval Dosage Definition (derived)           | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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Name of Medication HYDROXYZINE

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION OF  
DEPRESSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="checkbox"/>         |
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify   |                          |                                  |
| Start date (dd MMM yyyy)                       | 02 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)               | 2                        |                                  |
| Interval Dosage Unit Number (derived)          | 1                        |                                  |
| Interval Dosage Definition (derived)           | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |



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Form: Prior/Concomitant Medication and Vaccination (8)

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Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION OF  
DEPRESSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (8)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="checkbox"/>         |
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 03 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)                   |                          | 3                                |
| Interval Dosage Unit Number (derived)              |                          | 1                                |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Form: Prior/Concomitant Medication and Vaccination (9)

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Name of Medication FLUOXETINE

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION OF  
DEPRESSION

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 ☐

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Form: Prior/Concomitant Medication and Vaccination (9)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="checkbox"/>         |
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | 05 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"/> |

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Form: Prior/Concomitant Medication and Vaccination (10)

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Name of Medication TRAZADONE

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION OF  
DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

HS

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (10)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intraocular              | <input type="checkbox"/>         |
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify   |                          |                                  |
| Start date (dd MMM yyyy)                       | 02 MAR 2021              |                                  |
| Start date completely unknown                  | False                    |                                  |
| Ongoing?                                       | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy)         |                          |                                  |
| Was this medication taken for solicited event? | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)               |                          |                                  |
| Interval Dosage Unit Number (derived)          |                          |                                  |
| Interval Dosage Definition (derived)           | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

US3312465

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 06 Apr 2021 02:47:02

Generated On: 09 Jun 2021 17:03:25

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3312465

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:03:25

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify



US3312465

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:03:25

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 ☐

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 20:47:22

Generated On: 09 Jun 2021 17:03:25

|  |  |
|--|--|
| SAEID  | USA-US300-2021-MRNA-1273-P301000021                              |
| Serious  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect                             | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event                                | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name                                      | CARLOS   |
| Investigator's Last Name                                       | FIERRO   |
| Site Address: Street   | 16300 COLLEGE BLVD   |
| Site Address: City   | SHAWNEE  |
| Site Address: State  | KS   |
| Site Address: Postal Code                                      | 66219  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)                             | 4  |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 20:47:22

Generated On: 09 Jun 2021 17:03:25

|   |  |
|---|--|
| SAEID   | USA-US300-2021-MRNA-1273-P301000021                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | CARLOS   |
| Investigator's Last Name  | FIERRO   |
| Site Address: Street  | 16300 COLLEGE BLVD   |
| Site Address: City  | SHAWNEE  |
| Site Address: State   | KS   |
| Site Address: Postal Code   | 66219  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 4  |
| Date of submission (Pre-filled from custom function)  | 29/MAR/2021 13:24  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 20:47:22

Generated On: 09 Jun 2021 17:03:25

|   |  |
|---|--|
| SAEID   | USA-US300-2021-MRNA-1273-P301000021                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | CARLOS   |
| Investigator's Last Name  | FIERRO   |
| Site Address: Street  | 16300 COLLEGE BLVD   |
| Site Address: City  | SHAWNEE  |
| Site Address: State   | KS   |
| Site Address: Postal Code   | 66219  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 4  |
| Date of submission (Pre-filled from custom function)  | 31/MAR/2021 17:00  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | False  |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 20:47:22

Generated On: 09 Jun 2021 17:03:25

|   |  |
|---|--|
| SAEID   | USA-US300-2021-MRNA-1273-P301000021                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | CARLOS   |
| Investigator's Last Name  | FIERRO   |
| Site Address: Street  | 16300 COLLEGE BLVD   |
| Site Address: City  | SHAWNEE  |
| Site Address: State   | KS   |
| Site Address: Postal Code   | 66219  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 4  |
| Date of submission (Pre-filled from custom function)  | 01/APR/2021 05:54  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form (4)

Data signed: (b) (4) 22 Apr 2021 20:47:22

Generated On: 09 Jun 2021 17:03:25

|   |  |
|---|--|
| SAEID   | USA-US300-2021-MRNA-1273-P301000021                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | CARLOS   |
| Investigator's Last Name  | FIERRO   |
| Site Address: Street  | 16300 COLLEGE BLVD   |
| Site Address: City  | SHAWNEE  |
| Site Address: State   | KS   |
| Site Address: Postal Code   | 66219  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 4  |
| Date of submission (Pre-filled from custom function)  | 09/APR/2021 10:13  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form (5)

Data signed: (b) (4) 22 Apr 2021 20:47:22

Generated On: 09 Jun 2021 17:03:25

|   |  |
|---|--|
| SAEID   | USA-US300-2021-MRNA-1273-P301000021                              |
| Serious   | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Death   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Life threatening  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization  | Yes <input checked="" type="radio"/><br>No <input type="radio"/> |
| Persistent or significant disability or incapacity  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Other medically important event   | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| Investigator's First Name   | CARLOS   |
| Investigator's Last Name  | FIERRO   |
| Site Address: Street  | 16300 COLLEGE BLVD   |
| Site Address: City  | SHAWNEE  |
| Site Address: State   | KS   |
| Site Address: Postal Code   | 66219  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 4  |
| Date of submission (Pre-filled from custom function)  | 16/APR/2021 09:50  |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True   |

Audit

US3312465 (Prod: Johnson County Clin-Trials)



**US3312465**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:03:25**

[Participant ID](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)                                  | 06 Apr 2021 02:47:03 |
| User entered 'US3312465'  | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 02 Sep 2020 19:14:42 |

US3312465

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Was this visit performed?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | Christa Estrada (b) (4) | 02 Sep 2020 20:34:13 |

US3312465

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                                       | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                                  | 15 Feb 2021 22:50:13 |
| User entered '02 SEP 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 02 Sep 2020 19:14:43 |

US3312465

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[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 18:38:42 |
| User signature succeeded.      | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered 'Clinic (Clinic)' | Christa Estrada (b) (4) | 02 Sep 2020 20:34:13 |

US3312465

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'SCRN' | System           | 02 Sep 2020 20:34:13 |

US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

Date of Birth (MMM yyyy)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                                       | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                                  | 15 Feb 2021 22:50:13 |
| User entered (b) (6) 2002' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 02 Sep 2020 19:14:44 |

US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

[Age](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)              | 15 Feb 2021 22:50:13 |
| User entered '18'         | (b) (4)<br>Christa Estrada (b) (4) | 02 Sep 2020 20:34:29 |

US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'YEARS' | System           | 02 Sep 2020 20:34:29 |



US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '18' | System           | 02 Sep 2020 20:34:43 |

US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

[Sex](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered 'Male (M)'   | Christa Estrada (b) (4) | 02 Sep 2020 20:34:29 |

US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

[Ethnicity](#)

| Audit  | User                    | Time (GMT)           |
|--|-------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded.                                      | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | Christa Estrada (b) (4) | 02 Sep 2020 20:34:29 |

US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

White

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered 'I'          | Christa Estrada (b) (4) | 02 Sep 2020 20:34:29 |

US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

[Black](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered '0'          | Christa Estrada (b) (4) | 02 Sep 2020 20:34:29 |

US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

[Asian](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered '0'          | Christa Estrada (b) (4) | 02 Sep 2020 20:34:29 |

US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

[American Indian or Alaska Native](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered '0'          | Christa Estrada (b) (4) | 02 Sep 2020 20:34:29 |

US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered '0'          | Christa Estrada (b) (4) | 02 Sep 2020 20:34:29 |



US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

[Other](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered '0'          | Christa Estrada (b) (4) | 02 Sep 2020 20:34:29 |

US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

If race is Other, specify

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)              | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Christa Estrada (b) (4) | 02 Sep 2020 20:34:29 |

US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

Unknown

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered '0'          | Christa Estrada (b) (4) | 02 Sep 2020 20:34:29 |

US3312465

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:03:25

[Not reported](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered '0'          | Christa Estrada (b) (4) | 02 Sep 2020 20:34:29 |

US3312465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:25

Date of Informed Consent (*dd MMM yyyy*)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)              | 15 Feb 2021 22:50:13 |
| User entered '2 Sep 2020' | (b) (4)<br>Christa Estrada (b) (4) | 02 Sep 2020 20:34:43 |

US3312465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:25

[Month and Year of Informed Consent \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Sep 2020' | System           | 02 Sep 2020 20:34:43 |

US3312465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:25

[Year of Informed Consent \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2020' | System           | 02 Sep 2020 20:34:43 |

US3312465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:25

[Protocol Version](#)

| Audit                          | User                    | Time (GMT)           |
|--------------------------------|-------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded.      | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered 'Amendment 3 (3)' | Christa Estrada (b) (4) | 02 Sep 2020 20:34:43 |



US3312465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:25

[Was participant enrolled in the study?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | Christa Estrada (b) (4) | 02 Sep 2020 20:34:43 |

US3312465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:25

If No, indicate reason for screen fail

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered empty.       | Christa Estrada (b) (4) | 02 Sep 2020 20:34:43 |

US3312465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:25

If reason for screen fail is Other, specify

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered empty.       | Christa Estrada (b) (4) | 02 Sep 2020 20:34:43 |

US3312465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:25

[Was this participant screened previously?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | Christa Estrada (b) (4) | 02 Sep 2020 20:34:43 |

US3312465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:25

[If Yes, previous participant number](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                                       | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                                  | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 02 Sep 2020 19:14:43 |

US3312465

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:03:25

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'I'  | System           | 02 Sep 2020 20:34:53 |

US3312465

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:03:25

[Did the participant meet all eligibility criteria?](#)

| Audit                     | User                    | Time (GMT)           |
|---------------------------|-------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)        | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | Christa Estrada (b) (4) | 02 Sep 2020 20:34:53 |

US3312465

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:03:25

[Were any significant conditions reported?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:13:27 |



US3312465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:25

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| 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)  | 22 Sep 2020 23:14:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 22 Sep 2020 23:14:40 |
| Data point term sent to Coder  | System                | 22 Sep 2020 23:13:40 |
| User entered 'anxiety'   | Karol Moore (b) (4)   | 22 Sep 2020 23:13:39 |

US3312465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:25

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'un UNK 2016' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:13:39 |

US3312465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:25

[Start date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:13:39 |

US3312465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:25

[Condition ongoing at study entry](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:13:39 |

US3312465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:25

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:13:39 |

US3312465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:25

[Stop date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:13:39 |

US3312465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:25

Start Month and Year (derived)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2016' | System           | 22 Sep 2020 23:13:39 |

**US3312465**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2016' | System           | 22 Sep 2020 23:13:39 |



**US3312465**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 22 Sep 2020 23:13:39 |

US3312465

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:03:25

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 22 Sep 2020 23:13:39 |

US3312465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:25

Condition

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User signature succeeded.   | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0. | Coder Import (b) (4)  | 22 Sep 2020 23:15:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 22 Sep 2020 23:15:42 |
| Data point term sent to Coder   | System                | 22 Sep 2020 23:14:41 |
| User entered 'asthma'   | Karol Moore (b) (4)   | 22 Sep 2020 23:13:47 |

US3312465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:25

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'un UNK 2018' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:13:47 |

US3312465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:25

[Start date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:13:47 |

US3312465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:25

[Condition ongoing at study entry](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:13:47 |

US3312465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:25

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:13:47 |

US3312465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:25

[Stop date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:13:47 |



US3312465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:25

Start Month and Year (derived)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2018' | System           | 22 Sep 2020 23:13:47 |

US3312465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:25

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2018' | System           | 22 Sep 2020 23:13:47 |

US3312465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:25

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 22 Sep 2020 23:13:47 |

US3312465

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:03:25

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 22 Sep 2020 23:13:47 |

US3312465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:25

Condition

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User signature succeeded.   | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| 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)  | 22 Sep 2020 23:15:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 22 Sep 2020 23:15:42 |
| Data point term sent to Coder   | System                | 22 Sep 2020 23:14:41 |
| User entered 'bronchitis'   | Karol Moore (b) (4)   | 22 Sep 2020 23:14:00 |

US3312465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:25

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'un UNK 2018' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:14:00 |

US3312465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:25

[Start date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:14:00 |

US3312465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:25

[Condition ongoing at study entry](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:14:00 |



US3312465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:25

If No, please specify the stop date (dd MMM yyyy)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'un UNK 2018' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:14:00 |

US3312465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:25

[Stop date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:14:00 |

US3312465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:25

Start Month and Year (derived)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2018' | System           | 22 Sep 2020 23:14:00 |

US3312465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:25

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2018' | System           | 22 Sep 2020 23:14:00 |

US3312465

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:03:25

[Stop Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2018' | System           | 22 Sep 2020 23:14:00 |

**US3312465**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:03:25**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2018' | System           | 22 Sep 2020 23:14:00 |

US3312465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:25

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User signature succeeded.   | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Bullous conditions, PT: Blister, LLT: Blister - version MedDRA\\23.0. | Coder Import (b) (4)  | 30 Sep 2020 10:18:49 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)  | 30 Sep 2020 10:18:49 |
| Data point term sent to Coder   | System                | 22 Sep 2020 23:15:42 |
| User entered 'right second finger blister'  | Karol Moore (b) (4)   | 22 Sep 2020 23:14:58 |

US3312465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:25

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '31 Aug 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:14:58 |



US3312465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:25

[Start date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:14:58 |

US3312465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:25

[Condition ongoing at study entry](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System). | (b) (4)               | 22 Sep 2020 23:16:01 |
| User entered 'Yes (Y)' reason for change: Data Entry Error   | Karol Moore (b) (4)   | 22 Sep 2020 23:16:01 |
| User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System). | (b) (4)               | 22 Sep 2020 23:14:58 |
| User entered 'No (N)'  | System                | 22 Sep 2020 23:14:58 |
|  | Karol Moore (b) (4)   | 22 Sep 2020 23:14:58 |
|  | (b) (4)               |                      |

US3312465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:25

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:14:58 |

US3312465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:25

[Stop date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:14:58 |

US3312465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:25

Start Month and Year (derived)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Aug 2020' | System           | 22 Sep 2020 23:14:58 |

US3312465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:25

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2020' | System           | 22 Sep 2020 23:14:58 |

US3312465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:25

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 22 Sep 2020 23:14:58 |

US3312465

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:03:25

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 22 Sep 2020 23:14:58 |



US3312465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:25

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0. | Coder Import (b) (4)  | 22 Sep 2020 23:16:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 22 Sep 2020 23:16:43 |
| Data point term sent to Coder  | System                | 22 Sep 2020 23:15:42 |
| User entered 'adderall allergy'  | Karol Moore (b) (4)   | 22 Sep 2020 23:15:36 |

US3312465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:25

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'un UNK 2010' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:15:36 |

US3312465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:25

[Start date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:15:36 |

US3312465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:25

[Condition ongoing at study entry](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:15:36 |

US3312465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:25

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4) | 22 Sep 2020 23:15:36 |

US3312465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:25

[Stop date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:15:36 |

US3312465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:25

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2010' | System           | 22 Sep 2020 23:15:36 |

US3312465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:25

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2010' | System           | 22 Sep 2020 23:15:36 |



US3312465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:25

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 22 Sep 2020 23:15:36 |

US3312465

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:03:25

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 22 Sep 2020 23:15:36 |

US3312465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:25

Condition

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User signature succeeded.   | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User coded data point as SOC: Psychiatric disorders, HLG: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\23.0. | Coder Import (b) (4)  | 22 Sep 2020 23:17:43 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.   | Coder Import (b) (4)  | 22 Sep 2020 23:17:43 |
| Data point term sent to Coder   | System                | 22 Sep 2020 23:16:42 |
| User entered 'attention deficit disorder'   | Karol Moore (b) (4)   | 22 Sep 2020 23:15:51 |

US3312465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:25

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'un UNK 2010' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:15:51 |

US3312465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:25

[Start date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:15:51 |

US3312465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:25

[Condition ongoing at study entry](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:15:51 |

US3312465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:25

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:15:51 |

US3312465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:25

[Stop date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:15:51 |



US3312465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:25

Start Month and Year (derived)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2010' | System           | 22 Sep 2020 23:15:51 |

US3312465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:25

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2010' | System           | 22 Sep 2020 23:15:51 |

US3312465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:25

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 22 Sep 2020 23:15:51 |

US3312465

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:03:25

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 22 Sep 2020 23:15:51 |

US3312465

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:25

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User signature succeeded.   | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0. | Coder Import (b) (4)  | 04 Feb 2021 19:36:52 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 04 Feb 2021 19:36:52 |
| Data point term sent to Coder   | System                | 04 Feb 2021 19:36:28 |
| User entered 'depression'   | (b) (4), (b) (6)      | 04 Feb 2021 19:36:12 |

US3312465

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:25

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'un UNK 2016' | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:36:12 |

US3312465

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:25

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:36:12 |

US3312465

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:25

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:36:12 |



US3312465

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:25

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:36:12 |

US3312465

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:25

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:36:12 |

US3312465

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:25

Start Month and Year (derived)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2016' | System           | 04 Feb 2021 19:36:12 |

US3312465

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:25

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2016' | System           | 04 Feb 2021 19:36:12 |

US3312465

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:25

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 04 Feb 2021 19:36:12 |

US3312465

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:03:25

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 04 Feb 2021 19:36:12 |

US3312465

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:25

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User signature succeeded.   | Carlos Fierro (b) (4) | 08 Apr 2021 16:15:49 |
| User coded data point as SOC: Psychiatric disorders, HLG: Anxiety disorders and symptoms, HLT: Fear symptoms and phobic disorders (incl social phobia), PT: Social anxiety disorder, LLT: Social anxiety disorder - version MedDRA\\23.0. | Coder Import (b) (4)  | 08 Apr 2021 16:04:50 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 08 Apr 2021 16:04:50 |
| Data point term sent to Coder   | System                | 08 Apr 2021 16:03:24 |
| User entered 'social anxiety disorder'  | (b) (4), (b) (6)      | 08 Apr 2021 16:03:05 |

US3312465

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:25

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'un UNK 2016' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:03:05 |



US3312465

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:25

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:03:05 |

US3312465

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:25

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:03:05 |

US3312465

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:25

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:03:05 |

US3312465

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:25

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:03:05 |

US3312465

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:25

Start Month and Year (derived)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2016' | System           | 08 Apr 2021 16:03:05 |

US3312465

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:25

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2016' | System           | 08 Apr 2021 16:03:05 |

US3312465

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:25

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 08 Apr 2021 16:03:05 |

US3312465

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:03:25

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 08 Apr 2021 16:03:05 |



US3312465

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:25

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User signature succeeded.   | Carlos Fierro (b) (4) | 08 Apr 2021 16:15:49 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Panic attacks and disorders, PT: Panic attack, LLT: Panic attacks - version MedDRA\\23.0. | Coder Import (b) (4)  | 08 Apr 2021 16:05:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)  | 08 Apr 2021 16:05:53 |
| Data point term sent to Coder   | System                | 08 Apr 2021 16:04:25 |
| User entered 'panic attacks'  | (b) (4), (b) (6)      | 08 Apr 2021 16:03:33 |

US3312465

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:25

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'un UNK 2016' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:03:33 |

US3312465

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:25

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:03:33 |

US3312465

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:25

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:03:33 |

US3312465

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:25

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:03:33 |

US3312465

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:25

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:03:33 |

US3312465

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:25

Start Month and Year (derived)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2016' | System           | 08 Apr 2021 16:03:33 |

US3312465

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:25

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2016' | System           | 08 Apr 2021 16:03:33 |



US3312465

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:03:25

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 08 Apr 2021 16:03:33 |

**US3312465**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 08 Apr 2021 16:03:33 |

US3312465

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:25

[Condition](#)

| Audit   | User                             | Time (GMT)           |
|---|----------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                 | 27 Apr 2021 18:38:42 |
| User coded data point as SOC: Psychiatric disorders, HLT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicide attempt, LLT: Suicide attempt - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 09 Apr 2021 05:11:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)  | 09 Apr 2021 05:11:41 |
| User signature succeeded.   | Carlos Fierro (b) (4)<br>(b) (4) | 08 Apr 2021 16:15:49 |
| Data point term sent to Coder   | System                           | 08 Apr 2021 16:05:28 |
| User entered 'suicide attempt (x4)'   | (b) (4), (b) (6)                 | 08 Apr 2021 16:04:50 |

US3312465

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:25

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'un UNK 2016' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:04:50 |

US3312465

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:25

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:04:50 |

US3312465

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:25

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:04:50 |

US3312465

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:25

If No, please specify the stop date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'un UNK 2020' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:04:50 |

US3312465

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:25

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:04:50 |



**US3312465**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2016' | System           | 08 Apr 2021 16:04:50 |

US3312465

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:25

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2016' | System           | 08 Apr 2021 16:04:50 |

US3312465

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:03:25

[Stop Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2020' | System           | 08 Apr 2021 16:04:50 |

**US3312465**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2020' | System           | 08 Apr 2021 16:04:50 |

US3312465

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:25

[Condition](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4) | 15 Apr 2021 19:46:46 |
| User coded data point as SOC: Psychiatric disorders, HLT: Substance related and addictive disorders, PT: Alcohol use disorder, LLT: Alcohol use disorder - version MedDRA\\23.0. | Coder Import (b) (4)  | 15 Apr 2021 19:08:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)  | 15 Apr 2021 19:08:39 |
| Data point term sent to Coder  | System                | 15 Apr 2021 19:07:15 |
| User entered 'ALCOHOL USE DISORDER'  | Karol Moore (b) (4)   | 15 Apr 2021 19:07:08 |

US3312465

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:25

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Apr 2021 19:46:46 |
| User entered 'UN UNK 2016' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:07:08 |

US3312465

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:25

[Start date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Apr 2021 19:46:46 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:07:08 |

US3312465

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:25

[Condition ongoing at study entry](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Apr 2021 19:46:46 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:07:08 |



US3312465

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:25

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 15 Apr 2021 19:46:46 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4) | 15 Apr 2021 19:07:08 |

US3312465

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:25

[Stop date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Apr 2021 19:46:46 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:07:08 |

US3312465

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:25

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2016' | System           | 15 Apr 2021 19:07:08 |

US3312465

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:25

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2016' | System           | 15 Apr 2021 19:07:08 |

US3312465

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:25

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 15 Apr 2021 19:07:08 |

US3312465

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:03:25

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 15 Apr 2021 19:07:08 |

US3312465

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:25

Condition

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                 | 27 Apr 2021 18:38:42 |
| User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Substance use disorder, LLT: Substance use disorder - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 19 Apr 2021 11:22:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)  | 19 Apr 2021 11:22:50 |
| User signature succeeded.  | Carlos Fierro (b) (4)<br>(b) (4) | 15 Apr 2021 19:46:46 |
| Data point term sent to Coder  | System                           | 15 Apr 2021 19:08:18 |
| User entered 'CANNIBIS USE DISORDER'   | Karol Moore (b) (4)<br>(b) (4)   | 15 Apr 2021 19:07:29 |

US3312465

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:25

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Apr 2021 19:46:46 |
| User entered 'UN UNK 2016' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:07:29 |



US3312465

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:25

[Start date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Apr 2021 19:46:46 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:07:29 |

US3312465

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:25

[Condition ongoing at study entry](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Apr 2021 19:46:46 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:07:29 |

US3312465

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:25

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 15 Apr 2021 19:46:46 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4) | 15 Apr 2021 19:07:29 |

US3312465

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:25

[Stop date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Apr 2021 19:46:46 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:07:29 |

US3312465

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:25

Start Month and Year (derived)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2016' | System           | 15 Apr 2021 19:07:29 |

US3312465

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:25

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2016' | System           | 15 Apr 2021 19:07:29 |

US3312465

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:25

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 15 Apr 2021 19:07:29 |

US3312465

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:03:25

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 15 Apr 2021 19:07:29 |



US3312465

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:25

[Condition](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug abuse, LLT: Tranquillizer abuse - version MedDRA\\23.0. | Coder Import (b) (4)  | 16 Apr 2021 11:31:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | (b) (4)               |                      |
| User signature succeeded.   | Coder Import (b) (4)  | 16 Apr 2021 11:31:44 |
|   | (b) (4)               |                      |
|   | Carlos Fierro (b) (4) | 15 Apr 2021 19:46:46 |
|   | (b) (4)               |                      |
| Data point term sent to Coder   | System                | 15 Apr 2021 19:08:16 |
| User entered 'BENZODIAZEPINEABUSE'  | Karol Moore (b) (4)   | 15 Apr 2021 19:08:10 |
|   | (b) (4)               |                      |

US3312465

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:25

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Apr 2021 19:46:46 |
| User entered 'UN UNK 2016' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:08:10 |

US3312465

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:25

[Start date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Apr 2021 19:46:46 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:08:10 |

US3312465

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:25

[Condition ongoing at study entry](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Apr 2021 19:46:46 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:08:10 |

US3312465

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:25

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 15 Apr 2021 19:46:46 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4) | 15 Apr 2021 19:08:10 |

US3312465

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:25

[Stop date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Apr 2021 19:46:46 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:08:10 |

US3312465

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:25

Start Month and Year (derived)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'Jan 2016' | System           | 15 Apr 2021 19:08:10 |

US3312465

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:25

Start Year (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '2016' | System           | 15 Apr 2021 19:08:10 |



US3312465

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:25

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 15 Apr 2021 19:08:10 |

US3312465

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:03:25

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered empty. | System           | 15 Apr 2021 19:08:10 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Were vital signs assessed?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '02 Sep 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Time of assessment (00:00-23:59)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '14:27'      | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '02 Sep 2020 14:27' | System           | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Height (xxx.x)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered '74.0' in    | (b) (4)               | 22 Sep 2020 23:16:36 |
| DataPoint set to visible. | Karol Moore (b) (4)   | 02 Sep 2020 20:34:53 |
|                           | (b) (4)               |                      |
|                           | System                |                      |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Weight (xxx.x)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered '252.8' lb   | (b) (4)<br>Karol Moore (b) (4) | 22 Sep 2020 23:16:36 |
| DataPoint set to visible. | (b) (4)<br>System              | 02 Sep 2020 20:34:53 |



US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered '32.52547'   | System           | 22 Sep 2020 23:16:36 |
| DataPoint set to visible. | System           | 02 Sep 2020 20:34:53 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'kg/m2'      | System           | 22 Sep 2020 23:16:36 |
| DataPoint set to visible. | System           | 02 Sep 2020 20:34:53 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Temperature (xxx.x)

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)               | 27 Apr 2021 18:38:42 |
| User signature succeeded.                | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered missing code ND - Not Done. | (b) (4)<br>Karol Moore (b) (4) | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Route of measurement](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Oral (Oral)' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[If Other, specify](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Pulse \(xxx\)](#)

| Audit                                    | User                                      | Time (GMT)           |
|--|---|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.                | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered missing code ND - Not Done. | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'bpm' | System           | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate \(xxx\)](#)

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)               | 27 Apr 2021 18:38:42 |
| User signature succeeded.                | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered missing code ND - Not Done. | (b) (4)<br>Karol Moore (b) (4) | 22 Sep 2020 23:16:36 |



US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'breaths/min' | System           | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Systolic Blood Pressure (xxx)

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)               | 27 Apr 2021 18:38:42 |
| User signature succeeded.                | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered missing code ND - Not Done. | (b) (4)<br>Karol Moore (b) (4) | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'mmHg' | System           | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure (xxx)

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)               | 27 Apr 2021 18:38:42 |
| User signature succeeded.                | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered missing code ND - Not Done. | (b) (4)<br>Karol Moore (b) (4) | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
| User entered 'mmHg' | System           | 22 Sep 2020 23:16:36 |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
|                   |                  |                      |

US3312465

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 18:38:42 |
|                   |                  |                      |

US3312465

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:25

[Was the physical examination performed?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:16:46 |



US3312465

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:25

Date of examination (dd MMM yyyy)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '02 Sep 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:16:46 |

US3312465

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

**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 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

US3312465

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

**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 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

**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 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

**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 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

[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 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

[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 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

**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 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | Karol Moore (b) (4)   | 22 Sep 2020 23:17:19 |



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Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | Karol Moore (b) (4)   | 22 Sep 2020 23:17:19 |

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

**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 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | Karol Moore (b) (4)   | 22 Sep 2020 23:17:19 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

**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 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

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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 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

[Specify](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

No Risk Identified

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

US3312465

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

**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 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered '0'          | Karol Moore (b) (4)   | 22 Sep 2020 23:17:19 |

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Folder: Screening

Form: Risk of Exposure

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[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 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

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 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered '0'          | Karol Moore (b) (4)   | 22 Sep 2020 23:17:19 |

US3312465

Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

US3312465

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

[Other](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'I'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

US3312465

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:03:25

[Specify](#)

| Audit  | User                                      | Time (GMT)           |
|--|---|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                          | 27 Apr 2021 18:38:42 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'resides in community with ongoing person to person transmission' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:17:19 |

US3312465

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Was this visit performed?](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)              | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Christa Estrada (b) (4) | 02 Sep 2020 20:35:03 |

US3312465

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)              | 15 Feb 2021 22:50:13 |
| User entered '2 Sep 2020' | (b) (4)<br>Christa Estrada (b) (4) | 02 Sep 2020 20:35:03 |



US3312465

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[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 11:54:08 |
| User signature succeeded.      | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered 'Clinic (Clinic)' | Christa Estrada (b) (4) | 02 Sep 2020 20:35:03 |

US3312465

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered 'VISIT1' | System           | 02 Sep 2020 20:35:03 |

US3312465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:25

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

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                                       | 03 Apr 2021 11:54:08 |
| User signature succeeded.  | Carlos Fierro (b) (4)                                  | 15 Feb 2021 22:50:13 |
| User entered '02 SEP 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 02 Sep 2020 20:09:44 |

US3312465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:25

[What was the participant's randomization number?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                                       | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                                  | 15 Feb 2021 22:50:13 |
| User entered '111088'     | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 02 Sep 2020 20:09:44 |

US3312465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:25

[In what Cohort was the participant enrolled?](#)

| Audit   | User   | Time (GMT)           |
|---|--|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)                                       | 03 Apr 2021 11:54:08 |
| User signature succeeded.                             | Carlos Fierro (b) (4)                                  | 15 Feb 2021 22:50:13 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4)<br>(b) (4) | 02 Sep 2020 20:09:44 |

US3312465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:25

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 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | Christa Estrada (b) (4) | 02 Sep 2020 20:35:16 |

US3312465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:25

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 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | Christa Estrada (b) (4) | 02 Sep 2020 20:35:16 |

US3312465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:25

Severe obesity (body mass index > or = 40kg/m2

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                              | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                         | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Christa Estrada (b) (4)<br>(b) (4) | 02 Sep 2020 20:35:16 |



US3312465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:25

Diabetes (Type I, Type 2, or gestational)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)              | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Christa Estrada (b) (4) | 02 Sep 2020 20:35:16 |

US3312465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:25

[Liver Disease](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)              | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Christa Estrada (b) (4) | 02 Sep 2020 20:35:16 |

US3312465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:03:25

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)               | 03 Apr 2021 11:54:08 |
| User signature succeeded.                    | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'                        | (b) (4)<br>Karol Moore (b) (4) | 22 Sep 2020 23:17:25 |
| Amendment Manager: DataPoint set to visible. | (b) (4)<br>System              | 19 Sep 2020 04:59:05 |
| Amendment Manager inserted this DataPoint.   | System                         | 19 Sep 2020 04:59:04 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:25

[Height](#)

| Audit                                    | User                                      | Time (GMT)           |
|--|---|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded.                | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered missing code ND - Not Done. | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:25

Weight

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)               | 03 Apr 2021 11:54:08 |
| User signature succeeded.                | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered missing code ND - Not Done. | (b) (4)<br>Karol Moore (b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:25

Height

| Audit                                    | User                                      | Time (GMT)           |
|--|---|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded.                | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered missing code ND - Not Done. | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:25

Weight

| Audit                                    | User                                      | Time (GMT)           |
|--|---|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded.                | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered missing code ND - Not Done. | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Timepoint](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)    | 03 Apr 2021 11:54:08 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Karol Moore (b) (4) | 22 Sep 2020 23:18:14 |
|  | (b) (4)             |                      |



US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Were vital signs assessed?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '02 Sep 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

Time of assessment (00:00-23:59)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '14:27'      | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered '02 Sep 2020 14:27' | System           | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

Temperature (xxx.x)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '98.1' F     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Route of measurement](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Oral (Oral)' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[If Other, specify](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Pulse \(xxx\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '62'         | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |



US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered 'bpm' | System           | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '16'         | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered 'breaths/min' | System           | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

Systolic Blood Pressure (xxx)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '137'        | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered 'mmHg' | System           | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure (xxx)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '82'         | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered 'mmHg' | System           | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:25

[Height](#)

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)               | 03 Apr 2021 11:54:08 |
| User signature succeeded.                | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered missing code ND - Not Done. | (b) (4)<br>Karol Moore (b) (4) | 22 Sep 2020 23:18:14 |



US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:03:25

Weight

| Audit                                    | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)               | 03 Apr 2021 11:54:08 |
| User signature succeeded.                | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered missing code ND - Not Done. | (b) (4)<br>Karol Moore (b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Timepoint](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)               | 03 Apr 2021 11:54:08 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Were vital signs assessed?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '02 Sep 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

Time of assessment (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered '16:00'      | (b) (4)               | 22 Sep 2020 23:18:14 |
|                           | Karol Moore (b) (4)   |                      |
|                           | (b) (4)               |                      |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered '02 Sep 2020 16:00' | System           | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

Temperature (xxx.x)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '98.0' F     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Route of measurement](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Oral (Oral)' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |



US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[If Other, specify](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Pulse \(xxx\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '65'         | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered 'bpm' | System           | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '14'         | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered 'breaths/min' | System           | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

Systolic Blood Pressure (xxx)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '126'        | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered 'mmHg' | System           | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure (xxx)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '72'         | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:14 |



US3312465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered 'mmHg' | System           | 22 Sep 2020 23:18:14 |

US3312465

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:25

[Was the physical examination performed?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:28 |

US3312465

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:25

Date of examination (dd MMM yyyy)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:28 |

US3312465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

[Was study treatment given?](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)              | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Christa Estrada (b) (4) | 02 Sep 2020 20:35:37 |

US3312465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

[If No, reason not given](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)              | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Christa Estrada (b) (4) | 02 Sep 2020 20:35:37 |

US3312465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

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 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered empty.       | Christa Estrada (b) (4) | 02 Sep 2020 20:35:37 |

US3312465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

What was the treatment date? (dd MMM yyyy)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)              | 15 Feb 2021 22:50:13 |
| User entered '2 Sep 2020' | (b) (4)<br>Christa Estrada (b) (4) | 02 Sep 2020 20:35:37 |



US3312465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                               | Time (GMT)           |
|---------------------------|------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                   | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)              | 15 Feb 2021 22:50:13 |
| User entered '15:29'      | (b) (4)<br>Christa Estrada (b) (4) | 02 Sep 2020 20:35:37 |

US3312465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

[Treatment Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered '2 Sep 2020 15:29' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

[Which arm was used to give treatment?](#)

| Audit                              | User                    | Time (GMT)           |
|------------------------------------|-------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)        | 03 Apr 2021 11:54:08 |
| User signature succeeded.          | Carlos Fierro (b) (4)   | 15 Feb 2021 22:50:13 |
| User entered 'Left Arm (LEFT ARM)' | Christa Estrada (b) (4) | 02 Sep 2020 20:35:37 |

US3312465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered 'ONCE' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered 'INTRAMUSCULAR' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

[Was the sample collected?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:45 |

US3312465

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

Collection date (*dd MMM yyyy*)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '02 Sep 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:18:45 |

US3312465

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

Collection time (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered '14:54'      | (b) (4)               | 22 Sep 2020 23:18:45 |
|                           | Karol Moore (b) (4)   |                      |
|                           | (b) (4)               |                      |



US3312465

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

Collection date and time (derived)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered '02 Sep 2020 14:54' | System           | 22 Sep 2020 23:18:45 |

US3312465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:03:25

Collection date (*dd MMM yyyy*)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '02 Sep 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:00 |

US3312465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:25

[Lab Test](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)               | 03 Apr 2021 11:54:08 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:00 |

US3312465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:25

[Was the sample collected?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:00 |

US3312465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:25

Collection time (00:00 - 23:59)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '14:47'      | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:00 |

US3312465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:25

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered '02 Sep 2020 14:47' | System           | 22 Sep 2020 23:19:00 |

US3312465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:25

[Lab Test](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)               | 03 Apr 2021 11:54:08 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:00 |

US3312465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:25

[Was the sample collected?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:00 |



US3312465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:25

Collection time (00:00 - 23:59)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:00 |

US3312465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:25

Collection date and time (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered empty. | System           | 22 Sep 2020 23:19:00 |

US3312465

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:08 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:04 |

US3312465

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 11:54:08 |
| User entered 'I'  | System           | 22 Sep 2020 23:19:04 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:07', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '2fcd6365-5fd3-4fa2-aeb8-066a5bfbe97b' | System           | 02 Sep 2020 21:01:25 |
| User entered 'Yes (Y)'   | System           | 02 Sep 2020 21:01:25 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:13', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '2fcd6365-5fd3-4fa2-aeb8-066a5bfbe97b' | System           | 02 Sep 2020 21:01:25 |
| User entered '98.0'  | System           | 02 Sep 2020 21:01:25 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:18', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '2fcd6365-5fd3-4fa2-aeb8-066a5bfbe97b' | System           | 02 Sep 2020 21:01:25 |
| User entered 'No (N)'  | System           | 02 Sep 2020 21:01:25 |



US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:21', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '2fcd6365-5fd3-4fa2-aeb8-066a5bfbe97b' | System           | 02 Sep 2020 21:01:25 |
| User entered '02 Sep 2020 16:01'   | System           | 02 Sep 2020 21:01:25 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Sep 2020 15:49' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Sep 2020 18:19' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.                                | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 1, after vaccination (at home)' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:03:40', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '62f5b9e5-ac08-461d-991d-ccc42b52767d' | System           | 03 Sep 2020 02:04:08 |
| User entered 'Yes (Y)'   | System           | 03 Sep 2020 02:04:08 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:03:53', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '62f5b9e5-ac08-461d-991d-ccc42b52767d' | System           | 03 Sep 2020 02:04:08 |
| User entered '97.8'  | System           | 03 Sep 2020 02:04:08 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:03:57', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '62f5b9e5-ac08-461d-991d-ccc42b52767d' | System           | 03 Sep 2020 02:04:08 |
| User entered 'No (N)'  | System           | 03 Sep 2020 02:04:08 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '62f5b9e5-ac08-461d-991d-ccc42b52767d' | System           | 03 Sep 2020 02:04:08 |
| User entered '02 Sep 2020 21:04'   | System           | 03 Sep 2020 02:04:08 |



US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Sep 2020 19:14' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '03 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 2' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T21:59:26', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'f6f46fee-6da5-463a-b285-290fb11025a3' | System           | 04 Sep 2020 02:59:39 |
| User entered 'Yes (Y)'   | System           | 04 Sep 2020 02:59:39 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T21:59:31', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'f6f46fee-6da5-463a-b285-290fb11025a3' | System           | 04 Sep 2020 02:59:39 |
| User entered '97.8'  | System           | 04 Sep 2020 02:59:39 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T21:59:34', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'f6f46fee-6da5-463a-b285-290fb11025a3' | System           | 04 Sep 2020 02:59:39 |
| User entered 'No (N)'  | System           | 04 Sep 2020 02:59:39 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T21:59:37', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'f6f46fee-6da5-463a-b285-290fb11025a3' | System           | 04 Sep 2020 02:59:39 |
| User entered '03 Sep 2020 21:59'   | System           | 04 Sep 2020 02:59:39 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '03 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |



US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '04 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 3' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:07:29', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'c0def677-2822-41a0-890f-673dfe6ce220' | System           | 05 Sep 2020 01:07:42 |
| User entered 'Yes (Y)'   | System           | 05 Sep 2020 01:07:42 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:07:34', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'c0def677-2822-41a0-890f-673dfe6ce220' | System           | 05 Sep 2020 01:07:42 |
| User entered '98.1'  | System           | 05 Sep 2020 01:07:42 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:07:36', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'c0def677-2822-41a0-890f-673dfe6ce220' | System           | 05 Sep 2020 01:07:42 |
| User entered 'No (N)'  | System           | 05 Sep 2020 01:07:42 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:07:38', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'c0def677-2822-41a0-890f-673dfe6ce220' | System           | 05 Sep 2020 01:07:42 |
| User entered '04 Sep 2020 20:07'   | System           | 05 Sep 2020 01:07:42 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '04 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '05 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |



US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 4' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:49:51', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '981068cb-e5aa-4c61-9287-f1ca2a6c2931' | System           | 05 Sep 2020 23:50:05 |
| User entered 'Yes (Y)'   | System           | 05 Sep 2020 23:50:05 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:49:56', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '981068cb-e5aa-4c61-9287-f1ca2a6c2931' | System           | 05 Sep 2020 23:50:05 |
| User entered '97.9'  | System           | 05 Sep 2020 23:50:05 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:49:59', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '981068cb-e5aa-4c61-9287-f1ca2a6c2931' | System           | 05 Sep 2020 23:50:05 |
| User entered 'No (N)'  | System           | 05 Sep 2020 23:50:05 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:01', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '981068cb-e5aa-4c61-9287-f1ca2a6c2931' | System           | 05 Sep 2020 23:50:05 |
| User entered '05 Sep 2020 18:50'   | System           | 05 Sep 2020 23:50:05 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '05 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '06 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 5' | System           | 02 Sep 2020 20:35:37 |



US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:22:37', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cd6589bf-a973-4901-9602-73043cc69fec' | System           | 07 Sep 2020 01:22:50 |
| User entered 'Yes (Y)'   | System           | 07 Sep 2020 01:22:50 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:22:43', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cd6589bf-a973-4901-9602-73043cc69fec' | System           | 07 Sep 2020 01:22:50 |
| User entered '98.0'  | System           | 07 Sep 2020 01:22:50 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:22:45', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cd6589bf-a973-4901-9602-73043cc69fec' | System           | 07 Sep 2020 01:22:50 |
| User entered 'No (N)'  | System           | 07 Sep 2020 01:22:50 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:22:47', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cd6589bf-a973-4901-9602-73043cc69fec' | System           | 07 Sep 2020 01:22:50 |
| User entered '06 Sep 2020 20:22'   | System           | 07 Sep 2020 01:22:50 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '06 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '07 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 6' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:47:39', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8dfef330-3f2a-4823-a000-d39f16df62cf' | System           | 08 Sep 2020 01:47:54 |
| User entered 'Yes (Y)'   | System           | 08 Sep 2020 01:47:54 |



US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:47:47', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8dfef330-3f2a-4823-a000-d39f16df62cf' | System           | 08 Sep 2020 01:47:54 |
| User entered '98.4'  | System           | 08 Sep 2020 01:47:54 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:47:49', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8dfef330-3f2a-4823-a000-d39f16df62cf' | System           | 08 Sep 2020 01:47:54 |
| User entered 'No (N)'  | System           | 08 Sep 2020 01:47:54 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:47:51', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8dfef330-3f2a-4823-a000-d39f16df62cf' | System           | 08 Sep 2020 01:47:54 |
| User entered '07 Sep 2020 20:47'   | System           | 08 Sep 2020 01:47:54 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '07 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '08 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 7' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:29:38', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5b5deac9-24e2-4664-a73c-4c07405a0ac5' | System           | 09 Sep 2020 15:29:57 |
| User entered 'Yes (Y)'   | System           | 09 Sep 2020 15:29:57 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:29:46', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5b5deac9-24e2-4664-a73c-4c07405a0ac5' | System           | 09 Sep 2020 15:29:57 |
| User entered '98.0'  | System           | 09 Sep 2020 15:29:57 |



US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:29:50', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5b5deac9-24e2-4664-a73c-4c07405a0ac5' | System           | 09 Sep 2020 15:29:57 |
| User entered 'No (N)'  | System           | 09 Sep 2020 15:29:57 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:29:52', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5b5deac9-24e2-4664-a73c-4c07405a0ac5' | System           | 09 Sep 2020 15:29:57 |
| User entered '09 Sep 2020 10:29'   | System           | 09 Sep 2020 15:29:57 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '08 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '09 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:26', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '3b8fff99-7911-4da7-9be0-9073f8193550' | System           | 02 Sep 2020 21:01:42 |
| User entered 'None (1)'  | System           | 02 Sep 2020 21:01:42 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:29', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '3b8fff99-7911-4da7-9be0-9073f8193550' | System           | 02 Sep 2020 21:01:42 |
| User entered 'No (N)'  | System           | 02 Sep 2020 21:01:42 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:31', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '3b8fff99-7911-4da7-9be0-9073f8193550' | System           | 02 Sep 2020 21:01:42 |
| User entered 'No (N)'  | System           | 02 Sep 2020 21:01:42 |



US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:34', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '3b8fff99-7911-4da7-9be0-9073f8193550' | System           | 02 Sep 2020 21:01:42 |
| User entered 'None (1)'  | System           | 02 Sep 2020 21:01:42 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:36', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '3b8fff99-7911-4da7-9be0-9073f8193550' | System           | 02 Sep 2020 21:01:42 |
| User entered '02 Sep 2020 16:01'   | System           | 02 Sep 2020 21:01:42 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Sep 2020 15:49' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Sep 2020 18:19' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.                                | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 1, after vaccination (at home)' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:07', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '6f3e7669-2ea1-40a2-933b-54ecd3f839ae' | System           | 03 Sep 2020 02:04:20 |
| User entered 'None (1)'  | System           | 03 Sep 2020 02:04:20 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:10', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '6f3e7669-2ea1-40a2-933b-54ecd3f839ae' | System           | 03 Sep 2020 02:04:20 |
| User entered 'No (N)'  | System           | 03 Sep 2020 02:04:20 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:12', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '6f3e7669-2ea1-40a2-933b-54ecd3f839ae' | System           | 03 Sep 2020 02:04:20 |
| User entered 'No (N)'  | System           | 03 Sep 2020 02:04:20 |



US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:14', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '6f3e7669-2ea1-40a2-933b-54ecd3f839ae' | System           | 03 Sep 2020 02:04:20 |
| User entered 'None (1)'  | System           | 03 Sep 2020 02:04:20 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:17', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '6f3e7669-2ea1-40a2-933b-54ecd3f839ae' | System           | 03 Sep 2020 02:04:20 |
| User entered '02 Sep 2020 21:04'   | System           | 03 Sep 2020 02:04:20 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Sep 2020 19:14' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '03 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 2' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T21:59:44', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'efe23e9b-ab8a-4b11-b8be-279b8272db3e' | System           | 04 Sep 2020 02:59:55 |
| User entered 'Does not interfere with activity (2)'  | System           | 04 Sep 2020 02:59:55 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T21:59:46', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'efe23e9b-ab8a-4b11-b8be-279b8272db3e' | System           | 04 Sep 2020 02:59:55 |
| User entered 'No (N)'  | System           | 04 Sep 2020 02:59:55 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T21:59:48', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'efe23e9b-ab8a-4b11-b8be-279b8272db3e' | System           | 04 Sep 2020 02:59:55 |
| User entered 'No (N)'  | System           | 04 Sep 2020 02:59:55 |



US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T21:59:51', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'efe23e9b-ab8a-4b11-b8be-279b8272db3e' | System           | 04 Sep 2020 02:59:55 |
| User entered 'None (1)'  | System           | 04 Sep 2020 02:59:55 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T21:59:53', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'efe23e9b-ab8a-4b11-b8be-279b8272db3e' | System           | 04 Sep 2020 02:59:55 |
| User entered '03 Sep 2020 21:59'   | System           | 04 Sep 2020 02:59:55 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '03 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '04 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 3' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:07:43', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '89cdf9fa-92de-43e8-a936-a188b7117abf' | System           | 05 Sep 2020 01:07:55 |
| User entered 'None (1)'  | System           | 05 Sep 2020 01:07:55 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:07:45', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '89cdf9fa-92de-43e8-a936-a188b7117abf' | System           | 05 Sep 2020 01:07:55 |
| User entered 'No (N)'  | System           | 05 Sep 2020 01:07:55 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:07:46', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '89cdf9fa-92de-43e8-a936-a188b7117abf' | System           | 05 Sep 2020 01:07:55 |
| User entered 'No (N)'  | System           | 05 Sep 2020 01:07:55 |



US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:07:48', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '89cdf9fa-92de-43e8-a936-a188b7117abf' | System           | 05 Sep 2020 01:07:55 |
| User entered 'None (1)'  | System           | 05 Sep 2020 01:07:55 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:07:50', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '89cdf9fa-92de-43e8-a936-a188b7117abf' | System           | 05 Sep 2020 01:07:55 |
| User entered '04 Sep 2020 20:07'   | System           | 05 Sep 2020 01:07:55 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '04 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '05 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 4' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:05', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'a6a71167-4b5e-4333-85b2-55366a5411d7' | System           | 05 Sep 2020 23:50:38 |
| User entered 'Does not interfere with activity (2)'  | System           | 05 Sep 2020 23:50:38 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:08', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'a6a71167-4b5e-4333-85b2-55366a5411d7' | System           | 05 Sep 2020 23:50:38 |
| User entered 'No (N)'  | System           | 05 Sep 2020 23:50:38 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:10', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'a6a71167-4b5e-4333-85b2-55366a5411d7' | System           | 05 Sep 2020 23:50:38 |
| User entered 'No (N)'  | System           | 05 Sep 2020 23:50:38 |



US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:12', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'a6a71167-4b5e-4333-85b2-55366a5411d7' | System           | 05 Sep 2020 23:50:38 |
| User entered 'None (1)'  | System           | 05 Sep 2020 23:50:38 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:36', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'a6a71167-4b5e-4333-85b2-55366a5411d7' | System           | 05 Sep 2020 23:50:38 |
| User entered '05 Sep 2020 18:50'   | System           | 05 Sep 2020 23:50:38 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '05 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '06 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 5' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:22:51', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '9fd3397e-64be-4f0b-951b-86ca1f9ddd85' | System           | 07 Sep 2020 01:23:02 |
| User entered 'None (1)'  | System           | 07 Sep 2020 01:23:02 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:22:53', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '9fd3397e-64be-4f0b-951b-86ca1f9ddd85' | System           | 07 Sep 2020 01:23:02 |
| User entered 'No (N)'  | System           | 07 Sep 2020 01:23:02 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:22:54', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '9fd3397e-64be-4f0b-951b-86ca1f9ddd85' | System           | 07 Sep 2020 01:23:02 |
| User entered 'No (N)'  | System           | 07 Sep 2020 01:23:02 |



US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:22:56', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '9fd3397e-64be-4f0b-951b-86ca1f9ddd85' | System           | 07 Sep 2020 01:23:02 |
| User entered 'None (1)'  | System           | 07 Sep 2020 01:23:02 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:22:58', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '9fd3397e-64be-4f0b-951b-86ca1f9ddd85' | System           | 07 Sep 2020 01:23:02 |
| User entered '06 Sep 2020 20:22'   | System           | 07 Sep 2020 01:23:02 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '06 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '07 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 6' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:47:54', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1c52a225-63f7-44d1-9b38-cd793048a204' | System           | 08 Sep 2020 01:48:06 |
| User entered 'None (1)'  | System           | 08 Sep 2020 01:48:06 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:47:56', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1c52a225-63f7-44d1-9b38-cd793048a204' | System           | 08 Sep 2020 01:48:06 |
| User entered 'No (N)'  | System           | 08 Sep 2020 01:48:06 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:47:57', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1c52a225-63f7-44d1-9b38-cd793048a204' | System           | 08 Sep 2020 01:48:06 |
| User entered 'No (N)'  | System           | 08 Sep 2020 01:48:06 |



US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:47:59', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1c52a225-63f7-44d1-9b38-cd793048a204' | System           | 08 Sep 2020 01:48:06 |
| User entered 'None (1)'  | System           | 08 Sep 2020 01:48:06 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:48:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1c52a225-63f7-44d1-9b38-cd793048a204' | System           | 08 Sep 2020 01:48:06 |
| User entered '07 Sep 2020 20:48'   | System           | 08 Sep 2020 01:48:06 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '07 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '08 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 7' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:30:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '0bd9c213-cd46-46e5-9344-69baf9bdce3' | System           | 09 Sep 2020 15:30:10 |
| User entered 'None (1)'   | System           | 09 Sep 2020 15:30:10 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:30:02', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '0bd9c213-cd46-46e5-9344-69bafe9bdce3' | System           | 09 Sep 2020 15:30:10 |
| User entered 'No (N)'  | System           | 09 Sep 2020 15:30:10 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

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

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:30:03', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '0bd9c213-cd46-46e5-9344-69baf9bdce3' | System           | 09 Sep 2020 15:30:10 |
| User entered 'No (N)'   | System           | 09 Sep 2020 15:30:10 |



US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:30:04', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '0bd9c213-cd46-46e5-9344-69baf9bdce3' | System           | 09 Sep 2020 15:30:10 |
| User entered 'None (1)'   | System           | 09 Sep 2020 15:30:10 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:30:06', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '0bd9c213-cd46-46e5-9344-69baf9bdce3' | System           | 09 Sep 2020 15:30:10 |
| User entered '09 Sep 2020 10:30'  | System           | 09 Sep 2020 15:30:10 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '08 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '09 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:40', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'f4437447-5884-41d1-a346-d0ea8a397f0d' | System           | 02 Sep 2020 21:02:04 |
| User entered 'None (0)'  | System           | 02 Sep 2020 21:02:04 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:45', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'f4437447-5884-41d1-a346-d0ea8a397f0d' | System           | 02 Sep 2020 21:02:04 |
| User entered 'None (0)'  | System           | 02 Sep 2020 21:02:04 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:47', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'f4437447-5884-41d1-a346-d0ea8a397f0d' | System           | 02 Sep 2020 21:02:04 |
| User entered 'None (0)'  | System           | 02 Sep 2020 21:02:04 |



US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:49', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'f4437447-5884-41d1-a346-d0ea8a397f0d' | System           | 02 Sep 2020 21:02:04 |
| User entered 'None (0)'  | System           | 02 Sep 2020 21:02:04 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:51', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'f4437447-5884-41d1-a346-d0ea8a397f0d' | System           | 02 Sep 2020 21:02:04 |
| User entered 'None (0)'  | System           | 02 Sep 2020 21:02:04 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:53', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'f4437447-5884-41d1-a346-d0ea8a397f0d' | System           | 02 Sep 2020 21:02:04 |
| User entered 'None (0)'  | System           | 02 Sep 2020 21:02:04 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:01:57', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'f4437447-5884-41d1-a346-d0ea8a397f0d' | System           | 02 Sep 2020 21:02:04 |
| User entered 'No (N)'  | System           | 02 Sep 2020 21:02:04 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T16:02:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'f4437447-5884-41d1-a346-d0ea8a397f0d' | System           | 02 Sep 2020 21:02:04 |
| User entered '02 Sep 2020 16:02'   | System           | 02 Sep 2020 21:02:04 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Sep 2020 15:49' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Sep 2020 18:19' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.                                | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 1, after vaccination (at home)' | System           | 02 Sep 2020 20:35:37 |



US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:23', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cb4416bc-74ef-4842-88e5-8330b6f5957e' | System           | 03 Sep 2020 02:04:46 |
| User entered 'None (0)'  | System           | 03 Sep 2020 02:04:46 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:26', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cb4416bc-74ef-4842-88e5-8330b6f5957e' | System           | 03 Sep 2020 02:04:46 |
| User entered 'None (0)'  | System           | 03 Sep 2020 02:04:46 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:30', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cb4416bc-74ef-4842-88e5-8330b6f5957e' | System           | 03 Sep 2020 02:04:46 |
| User entered 'None (0)'  | System           | 03 Sep 2020 02:04:46 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:33', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cb4416bc-74ef-4842-88e5-8330b6f5957e' | System           | 03 Sep 2020 02:04:46 |
| User entered 'None (0)'  | System           | 03 Sep 2020 02:04:46 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:35', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cb4416bc-74ef-4842-88e5-8330b6f5957e' | System           | 03 Sep 2020 02:04:46 |
| User entered 'None (0)'  | System           | 03 Sep 2020 02:04:46 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:36', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cb4416bc-74ef-4842-88e5-8330b6f5957e' | System           | 03 Sep 2020 02:04:46 |
| User entered 'None (0)'  | System           | 03 Sep 2020 02:04:46 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:41', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cb4416bc-74ef-4842-88e5-8330b6f5957e' | System           | 03 Sep 2020 02:04:46 |
| User entered 'No (N)'  | System           | 03 Sep 2020 02:04:46 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-02T21:04:43', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cb4416bc-74ef-4842-88e5-8330b6f5957e' | System           | 03 Sep 2020 02:04:46 |
| User entered '02 Sep 2020 21:04'   | System           | 03 Sep 2020 02:04:46 |



US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Sep 2020 19:14' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '03 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 2' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T21:59:57', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '4d48652c-32c2-40e8-8407-32b2f8b665ce' | System           | 04 Sep 2020 03:00:16 |
| User entered 'None (0)'  | System           | 04 Sep 2020 03:00:16 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T22:00:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '4d48652c-32c2-40e8-8407-32b2f8b665ce' | System           | 04 Sep 2020 03:00:16 |
| User entered 'No interference with activity (1)'   | System           | 04 Sep 2020 03:00:16 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T22:00:02', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '4d48652c-32c2-40e8-8407-32b2f8b665ce' | System           | 04 Sep 2020 03:00:16 |
| User entered 'None (0)'  | System           | 04 Sep 2020 03:00:16 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T22:00:04', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '4d48652c-32c2-40e8-8407-32b2f8b665ce' | System           | 04 Sep 2020 03:00:16 |
| User entered 'None (0)'  | System           | 04 Sep 2020 03:00:16 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T22:00:06', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '4d48652c-32c2-40e8-8407-32b2f8b665ce' | System           | 04 Sep 2020 03:00:16 |
| User entered 'None (0)'  | System           | 04 Sep 2020 03:00:16 |



US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T22:00:08', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '4d48652c-32c2-40e8-8407-32b2f8b665ce' | System           | 04 Sep 2020 03:00:16 |
| User entered 'None (0)'  | System           | 04 Sep 2020 03:00:16 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T22:00:10', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '4d48652c-32c2-40e8-8407-32b2f8b665ce' | System           | 04 Sep 2020 03:00:16 |
| User entered 'No (N)'  | System           | 04 Sep 2020 03:00:16 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-03T22:00:12', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '4d48652c-32c2-40e8-8407-32b2f8b665ce' | System           | 04 Sep 2020 03:00:16 |
| User entered '03 Sep 2020 22:00'   | System           | 04 Sep 2020 03:00:16 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '03 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '04 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 3' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:07:53', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '892ecdaf-282d-42e8-9c6e-82f4bec8934b' | System           | 05 Sep 2020 01:08:13 |
| User entered 'None (0)'  | System           | 05 Sep 2020 01:08:13 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:07:55', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '892ecdaf-282d-42e8-9c6e-82f4bec8934b' | System           | 05 Sep 2020 01:08:13 |
| User entered 'None (0)'  | System           | 05 Sep 2020 01:08:13 |



US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:07:57', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '892ecdaf-282d-42e8-9c6e-82f4bec8934b' | System           | 05 Sep 2020 01:08:13 |
| User entered 'None (0)'  | System           | 05 Sep 2020 01:08:13 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:07:59', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '892ecdaf-282d-42e8-9c6e-82f4bec8934b' | System           | 05 Sep 2020 01:08:13 |
| User entered 'None (0)'  | System           | 05 Sep 2020 01:08:13 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:08:02', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '892ecdaf-282d-42e8-9c6e-82f4bec8934b' | System           | 05 Sep 2020 01:08:13 |
| User entered 'None (0)'  | System           | 05 Sep 2020 01:08:13 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:08:04', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '892ecdaf-282d-42e8-9c6e-82f4bec8934b' | System           | 05 Sep 2020 01:08:13 |
| User entered 'None (0)'  | System           | 05 Sep 2020 01:08:13 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:08:06', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '892ecdaf-282d-42e8-9c6e-82f4bec8934b' | System           | 05 Sep 2020 01:08:13 |
| User entered 'No (N)'  | System           | 05 Sep 2020 01:08:13 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-04T20:08:08', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '892ecdaf-282d-42e8-9c6e-82f4bec8934b' | System           | 05 Sep 2020 01:08:13 |
| User entered '04 Sep 2020 20:08'   | System           | 05 Sep 2020 01:08:13 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '04 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '05 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |



US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 4' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:41', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd82a8619-304d-4aa0-8b42-58597966c427' | System           | 05 Sep 2020 23:50:56 |
| User entered 'None (0)'  | System           | 05 Sep 2020 23:50:56 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:42', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd82a8619-304d-4aa0-8b42-58597966c427' | System           | 05 Sep 2020 23:50:56 |
| User entered 'None (0)'  | System           | 05 Sep 2020 23:50:56 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:44', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd82a8619-304d-4aa0-8b42-58597966c427' | System           | 05 Sep 2020 23:50:56 |
| User entered 'None (0)'  | System           | 05 Sep 2020 23:50:56 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:46', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd82a8619-304d-4aa0-8b42-58597966c427' | System           | 05 Sep 2020 23:50:56 |
| User entered 'None (0)'  | System           | 05 Sep 2020 23:50:56 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:48', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd82a8619-304d-4aa0-8b42-58597966c427' | System           | 05 Sep 2020 23:50:56 |
| User entered 'None (0)'  | System           | 05 Sep 2020 23:50:56 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:49', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd82a8619-304d-4aa0-8b42-58597966c427' | System           | 05 Sep 2020 23:50:56 |
| User entered 'None (0)'  | System           | 05 Sep 2020 23:50:56 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:51', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd82a8619-304d-4aa0-8b42-58597966c427' | System           | 05 Sep 2020 23:50:56 |
| User entered 'No (N)'  | System           | 05 Sep 2020 23:50:56 |



US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-05T18:50:53', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd82a8619-304d-4aa0-8b42-58597966c427' | System           | 05 Sep 2020 23:50:56 |
| User entered '05 Sep 2020 18:50'   | System           | 05 Sep 2020 23:50:56 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '05 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '06 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 5' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:23:02', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5ffc6753-2ff2-4795-8adc-3f73e24d187d' | System           | 07 Sep 2020 01:23:19 |
| User entered 'None (0)'  | System           | 07 Sep 2020 01:23:19 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:23:04', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5ffc6753-2ff2-4795-8adc-3f73e24d187d' | System           | 07 Sep 2020 01:23:19 |
| User entered 'None (0)'  | System           | 07 Sep 2020 01:23:19 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:23:05', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5ffc6753-2ff2-4795-8adc-3f73e24d187d' | System           | 07 Sep 2020 01:23:19 |
| User entered 'None (0)'  | System           | 07 Sep 2020 01:23:19 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:23:07', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5ffc6753-2ff2-4795-8adc-3f73e24d187d' | System           | 07 Sep 2020 01:23:19 |
| User entered 'None (0)'  | System           | 07 Sep 2020 01:23:19 |



US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:23:08', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5ffc6753-2ff2-4795-8adc-3f73e24d187d' | System           | 07 Sep 2020 01:23:19 |
| User entered 'None (0)'  | System           | 07 Sep 2020 01:23:19 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:23:09', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5ffc6753-2ff2-4795-8adc-3f73e24d187d' | System           | 07 Sep 2020 01:23:19 |
| User entered 'None (0)'  | System           | 07 Sep 2020 01:23:19 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:23:11', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5ffc6753-2ff2-4795-8adc-3f73e24d187d' | System           | 07 Sep 2020 01:23:19 |
| User entered 'No (N)'  | System           | 07 Sep 2020 01:23:19 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-06T20:23:13', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5ffc6753-2ff2-4795-8adc-3f73e24d187d' | System           | 07 Sep 2020 01:23:19 |
| User entered '06 Sep 2020 20:23'   | System           | 07 Sep 2020 01:23:19 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '06 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '07 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 6' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:48:05', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8e5c4c91-7fba-41f7-b3f4-405fa75d3160' | System           | 08 Sep 2020 01:48:22 |
| User entered 'None (0)'  | System           | 08 Sep 2020 01:48:22 |



US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:48:06', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8e5c4c91-7fba-41f7-b3f4-405fa75d3160' | System           | 08 Sep 2020 01:48:22 |
| User entered 'None (0)'  | System           | 08 Sep 2020 01:48:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:48:08', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8e5c4c91-7fba-41f7-b3f4-405fa75d3160' | System           | 08 Sep 2020 01:48:22 |
| User entered 'None (0)'  | System           | 08 Sep 2020 01:48:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:48:09', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8e5c4c91-7fba-41f7-b3f4-405fa75d3160' | System           | 08 Sep 2020 01:48:22 |
| User entered 'None (0)'  | System           | 08 Sep 2020 01:48:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:48:11', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8e5c4c91-7fba-41f7-b3f4-405fa75d3160' | System           | 08 Sep 2020 01:48:22 |
| User entered 'None (0)'  | System           | 08 Sep 2020 01:48:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:48:12', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8e5c4c91-7fba-41f7-b3f4-405fa75d3160' | System           | 08 Sep 2020 01:48:22 |
| User entered 'None (0)'  | System           | 08 Sep 2020 01:48:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:48:15', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8e5c4c91-7fba-41f7-b3f4-405fa75d3160' | System           | 08 Sep 2020 01:48:22 |
| User entered 'No (N)'  | System           | 08 Sep 2020 01:48:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-07T20:48:17', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8e5c4c91-7fba-41f7-b3f4-405fa75d3160' | System           | 08 Sep 2020 01:48:22 |
| User entered '07 Sep 2020 20:48'   | System           | 08 Sep 2020 01:48:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '07 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |



US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '08 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 7' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:30:09', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '6e864fff-61e5-4a05-97d8-716601a7ea85' | System           | 09 Sep 2020 15:30:22 |
| User entered 'None (0)'  | System           | 09 Sep 2020 15:30:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:30:11', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '6e864fff-61e5-4a05-97d8-716601a7ea85' | System           | 09 Sep 2020 15:30:22 |
| User entered 'None (0)'  | System           | 09 Sep 2020 15:30:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:30:12', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '6e864fff-61e5-4a05-97d8-716601a7ea85' | System           | 09 Sep 2020 15:30:22 |
| User entered 'None (0)'  | System           | 09 Sep 2020 15:30:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:30:13', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '6e864fff-61e5-4a05-97d8-716601a7ea85' | System           | 09 Sep 2020 15:30:22 |
| User entered 'None (0)'  | System           | 09 Sep 2020 15:30:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:30:14', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '6e864fff-61e5-4a05-97d8-716601a7ea85' | System           | 09 Sep 2020 15:30:22 |
| User entered 'None (0)'  | System           | 09 Sep 2020 15:30:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:30:15', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '6e864fff-61e5-4a05-97d8-716601a7ea85' | System           | 09 Sep 2020 15:30:22 |
| User entered 'None (0)'  | System           | 09 Sep 2020 15:30:22 |



US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:30:17', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '6e864fff-61e5-4a05-97d8-716601a7ea85' | System           | 09 Sep 2020 15:30:22 |
| User entered 'No (N)'  | System           | 09 Sep 2020 15:30:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-09T10:30:19', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '6e864fff-61e5-4a05-97d8-716601a7ea85' | System           | 09 Sep 2020 15:30:22 |
| User entered '09 Sep 2020 10:30'   | System           | 09 Sep 2020 15:30:22 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '08 Sep 2020 12:00' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '09 Sep 2020 11:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Was Contact Attempted?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:06 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:16 |

US3312465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:06 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '10 Sep 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:16 |

US3312465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                      | Time (GMT)           |
|--|---|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:06 |
| User signature succeeded.                  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:16 |

US3312465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 Apr 2021 11:54:06 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)               | 22 Sep 2020 23:19:16 |
|                           | Karol Moore (b) (4)   |                      |
|                           | (b) (4)               |                      |



US3312465

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:06 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:20 |

US3312465

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 11:54:06 |
| User entered 'I'  | System           | 22 Sep 2020 23:19:20 |

US3312465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Was Contact Attempted?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:06 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:10 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:46 |

US3312465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:06 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:10 |
| User entered '16 Sep 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:46 |

US3312465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                      | Time (GMT)           |
|--|---|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:06 |
| User signature succeeded.                  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:10 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:46 |

US3312465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 03 Apr 2021 11:54:06 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:10 |
| User entered empty.       | (b) (4)               | 22 Sep 2020 23:19:46 |
|                           | Karol Moore (b) (4)   |                      |
|                           | (b) (4)               |                      |

US3312465

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 03 Apr 2021 11:54:06 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:10 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:19:49 |

US3312465

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 11:54:06 |
| User entered 'I'  | System           | 22 Sep 2020 23:19:49 |



US3312465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Was Contact Attempted?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 29 Apr 2021 10:46:36 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 23 Sep 2020 15:52:48 |

US3312465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 29 Apr 2021 10:46:36 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '23 Sep 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 23 Sep 2020 15:52:48 |

US3312465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                      | Time (GMT)           |
|--|---|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                          | 29 Apr 2021 10:46:36 |
| User signature succeeded.                  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 23 Sep 2020 15:52:48 |

US3312465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 10:46:36 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)               | 23 Sep 2020 15:52:48 |
|                           | Karol Moore (b) (4)   |                      |
|                           | (b) (4)               |                      |

US3312465

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 29 Apr 2021 10:46:36 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 23 Sep 2020 15:52:51 |

US3312465

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 10:46:36 |
| User entered 'I'  | System           | 23 Sep 2020 15:52:51 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 30 Sep 2020 18:57:40 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '30 Sep 2020' | (b) (4)<br>(b) (4), (b) (6) | 30 Sep 2020 18:57:40 |



US3312465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.      | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 30 Sep 2020 18:57:40 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'VISIT2' | System           | 30 Sep 2020 18:57:40 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Timepoint](#)

| Audit  | User                | Time (GMT)           |
|--|---------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)    | 28 Apr 2021 18:38:58 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Karol Moore (b) (4) | 17 Oct 2020 21:31:52 |
|  | (b) (4)             |                      |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Were vital signs assessed?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '30 Sep 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

Time of assessment (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered '12:57'      | (b) (4)               | 17 Oct 2020 21:31:52 |
|                           | Karol Moore (b) (4)   |                      |
|                           | (b) (4)               |                      |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered '30 Sep 2020 12:57' | System           | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

Temperature (xxx.x)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '98.0' F     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |



US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Route of measurement](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered 'Oral (Oral)' | (b) (4)               | 17 Oct 2020 21:31:52 |
|                            | Karol Moore (b) (4)   |                      |
|                            | (b) (4)               |                      |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[If Other, specify](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Pulse \(xxx\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '98'         | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'bpm' | System           | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '16'         | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'breaths/min' | System           | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

Systolic Blood Pressure (xxx)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '125'        | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'mmHg' | System           | 17 Oct 2020 21:31:52 |



US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure (xxx)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '72'         | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'mmHg' | System           | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Timepoint](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)               | 28 Apr 2021 18:38:58 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Were vital signs assessed?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered '30 Sep 2020' | (b) (4)               | 17 Oct 2020 21:31:52 |
|                            | Karol Moore (b) (4)   |                      |
|                            | (b) (4)               |                      |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

Time of assessment (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered '14:22'      | (b) (4)               | 17 Oct 2020 21:31:52 |
|                           | Karol Moore (b) (4)   |                      |
|                           | (b) (4)               |                      |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered '30 Sep 2020 14:22' | System           | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

Temperature (xxx.x)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered '97.9' F     | (b) (4)<br>Karol Moore (b) (4) | 17 Oct 2020 21:31:52 |



US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Route of measurement](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Oral (Oral)' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[If Other, specify](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Pulse \(xxx\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '75'         | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'bpm' | System           | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '14'         | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'breaths/min' | System           | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

Systolic Blood Pressure (xxx)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '122'        | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'mmHg' | System           | 17 Oct 2020 21:31:52 |



US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure (xxx)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '67'         | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'mmHg' | System           | 17 Oct 2020 21:31:52 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:25

[Was the physical examination performed?](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4) | 17 Oct 2020 21:32:10 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:25

Date of examination (dd MMM yyyy)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '30 Sep 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:32:10 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

[Was study treatment given?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 30 Sep 2020 18:58:02 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

If No, reason not given

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 30 Sep 2020 18:58:02 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

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

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 30 Sep 2020 18:58:02 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 30 Sep 2020 18:58:02 |



US3312465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '30 Sep 2020' | (b) (4)<br>(b) (4), (b) (6) | 30 Sep 2020 18:58:02 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '13:52'      | (b) (4)<br>(b) (4), (b) (6) | 30 Sep 2020 18:58:02 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered '30 Sep 2020 13:52' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

[Which arm was used to give treatment?](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.          | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4)<br>(b) (4), (b) (6) | 30 Sep 2020 18:58:02 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'ONCE' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:03:25

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'INTRAMUSCULAR' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

[Was the sample collected?](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4) | 17 Oct 2020 21:32:24 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

Collection date (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)               | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered '30 Sep 2020' | (b) (4)<br>Karol Moore (b) (4) | 17 Oct 2020 21:32:24 |



US3312465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

Collection time (00:00-23:59)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '13:25'      | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:32:24 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered '30 Sep 2020 13:25' | System           | 17 Oct 2020 21:32:24 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:03:25

Collection date (*dd MMM yyyy*)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '30 Sep 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:32:34 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:25

[Lab Test](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)               | 28 Apr 2021 18:38:58 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:32:34 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:25

[Was the sample collected?](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4) | 17 Oct 2020 21:32:34 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:25

Collection time (00:00 - 23:59)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered '13:16'      | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:32:34 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:03:25

Collection date and time (derived)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered '30 Sep 2020 13:16' | System           | 17 Oct 2020 21:32:34 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:25

[Lab Test](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)               | 28 Apr 2021 18:38:58 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:32:34 |



US3312465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:25

[Was the sample collected?](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4) | 17 Oct 2020 21:32:34 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:25

Collection time (00:00 - 23:59)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4) | 17 Oct 2020 21:32:34 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:03:25

Collection date and time (derived)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered empty. | System           | 17 Oct 2020 21:32:34 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 30 Sep 2020 18:58:10 |

US3312465

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'I'  | System           | 30 Sep 2020 18:58:10 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:24', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '3281f9e2-f131-4f23-83c8-740cd05dc1c1' | System           | 30 Sep 2020 19:21:42 |
| User entered 'Yes (Y)'   | System           | 30 Sep 2020 19:21:42 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:30', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '3281f9e2-f131-4f23-83c8-740cd05dc1c1' | System           | 30 Sep 2020 19:21:42 |
| User entered '97.9'  | System           | 30 Sep 2020 19:21:42 |



US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:33', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '3281f9e2-f131-4f23-83c8-740cd05dc1c1' | System           | 30 Sep 2020 19:21:42 |
| User entered 'No (N)'  | System           | 30 Sep 2020 19:21:42 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:36', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '3281f9e2-f131-4f23-83c8-740cd05dc1c1' | System           | 30 Sep 2020 19:21:42 |
| User entered '30 Sep 2020 14:21'   | System           | 30 Sep 2020 19:21:42 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '30 Sep 2020 14:12' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '30 Sep 2020 16:42' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.                                | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 1, after vaccination (at home)' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:09', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'dbb41f4f-adcd-488d-bda6-eceeb5fa0599' | System           | 01 Oct 2020 12:56:21 |
| User entered 'Yes (Y)'   | System           | 01 Oct 2020 12:56:21 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:13', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'dbb41f4f-adcd-488d-bda6-eceeb5fa0599' | System           | 01 Oct 2020 12:56:21 |
| User entered '98.0'  | System           | 01 Oct 2020 12:56:21 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:15', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'dbb41f4f-adcd-488d-bda6-eceeb5fa0599' | System           | 01 Oct 2020 12:56:21 |
| User entered 'No (N)'  | System           | 01 Oct 2020 12:56:21 |



US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:17', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'dbb41f4f-adcd-488d-bda6-eceeb5fa0599' | System           | 01 Oct 2020 12:56:21 |
| User entered '01 Oct 2020 07:56'   | System           | 01 Oct 2020 12:56:21 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '30 Sep 2020 17:37' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '01 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 2' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:30:43', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '85f2e2ce-9e6c-4975-895c-7b279e858265' | System           | 01 Oct 2020 17:30:58 |
| User entered 'Yes (Y)'   | System           | 01 Oct 2020 17:30:58 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:30:48', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '85f2e2ce-9e6c-4975-895c-7b279e858265' | System           | 01 Oct 2020 17:30:58 |
| User entered '98.0'  | System           | 01 Oct 2020 17:30:58 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:30:50', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '85f2e2ce-9e6c-4975-895c-7b279e858265' | System           | 01 Oct 2020 17:30:58 |
| User entered 'No (N)'  | System           | 01 Oct 2020 17:30:58 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:30:52', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '85f2e2ce-9e6c-4975-895c-7b279e858265' | System           | 01 Oct 2020 17:30:58 |
| User entered '01 Oct 2020 12:30'   | System           | 01 Oct 2020 17:30:58 |



US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '01 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 3' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |



US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '03 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 4' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:11:51', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd4468247-a007-4c2a-b530-217f7af0ac9c' | System           | 03 Oct 2020 23:12:05 |
| User entered 'Yes (Y)'   | System           | 03 Oct 2020 23:12:05 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:11:57', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd4468247-a007-4c2a-b530-217f7af0ac9c' | System           | 03 Oct 2020 23:12:05 |
| User entered '98.0'  | System           | 03 Oct 2020 23:12:05 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:11:59', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd4468247-a007-4c2a-b530-217f7af0ac9c' | System           | 03 Oct 2020 23:12:05 |
| User entered 'No (N)'  | System           | 03 Oct 2020 23:12:05 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:12:01', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd4468247-a007-4c2a-b530-217f7af0ac9c' | System           | 03 Oct 2020 23:12:05 |
| User entered '03 Oct 2020 18:12'   | System           | 03 Oct 2020 23:12:05 |



US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '03 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '04 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 5' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:01:36', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '3b746a29-9029-4fbd-8d4b-18fe975874b9' | System           | 04 Oct 2020 18:01:49 |
| User entered 'Yes (Y)'   | System           | 04 Oct 2020 18:01:49 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:01:41', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '3b746a29-9029-4fbd-8d4b-18fe975874b9' | System           | 04 Oct 2020 18:01:49 |
| User entered '97.6'  | System           | 04 Oct 2020 18:01:49 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:01:43', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '3b746a29-9029-4fbd-8d4b-18fe975874b9' | System           | 04 Oct 2020 18:01:49 |
| User entered 'No (N)'  | System           | 04 Oct 2020 18:01:49 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:01:45', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '3b746a29-9029-4fbd-8d4b-18fe975874b9' | System           | 04 Oct 2020 18:01:49 |
| User entered '04 Oct 2020 13:01'   | System           | 04 Oct 2020 18:01:49 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '04 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |



US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '05 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 6' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |



US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '05 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '06 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 7' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:52:43', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '0627f836-7b51-4f3d-9dd4-065f8c9b671c' | System           | 06 Oct 2020 19:52:56 |
| User entered 'Yes (Y)'   | System           | 06 Oct 2020 19:52:56 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:52:48', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '0627f836-7b51-4f3d-9dd4-065f8c9b671c' | System           | 06 Oct 2020 19:52:56 |
| User entered '96.9'  | System           | 06 Oct 2020 19:52:56 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:52:51', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '0627f836-7b51-4f3d-9dd4-065f8c9b671c' | System           | 06 Oct 2020 19:52:56 |
| User entered 'No (N)'  | System           | 06 Oct 2020 19:52:56 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:52:53', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '0627f836-7b51-4f3d-9dd4-065f8c9b671c' | System           | 06 Oct 2020 19:52:56 |
| User entered '06 Oct 2020 14:52'   | System           | 06 Oct 2020 19:52:56 |

US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '06 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |



US3312465

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '07 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:57', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1f57afb9-4789-4796-88f8-19477f7b6150' | System           | 30 Sep 2020 19:22:09 |
| User entered 'None (1)'  | System           | 30 Sep 2020 19:22:09 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:59', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1f57afb9-4789-4796-88f8-19477f7b6150' | System           | 30 Sep 2020 19:22:09 |
| User entered 'No (N)'  | System           | 30 Sep 2020 19:22:09 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:22:01', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1f57afb9-4789-4796-88f8-19477f7b6150' | System           | 30 Sep 2020 19:22:09 |
| User entered 'No (N)'  | System           | 30 Sep 2020 19:22:09 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:22:02', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1f57afb9-4789-4796-88f8-19477f7b6150' | System           | 30 Sep 2020 19:22:09 |
| User entered 'None (1)'  | System           | 30 Sep 2020 19:22:09 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:22:04', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1f57afb9-4789-4796-88f8-19477f7b6150' | System           | 30 Sep 2020 19:22:09 |
| User entered '30 Sep 2020 14:22'   | System           | 30 Sep 2020 19:22:09 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '30 Sep 2020 14:12' | System           | 30 Sep 2020 18:58:02 |



US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '30 Sep 2020 16:42' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.                                | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 1, after vaccination (at home)' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:21', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'c99f245e-2e17-4377-8395-471cf6bf13c3' | System           | 01 Oct 2020 12:56:33 |
| User entered 'None (1)'  | System           | 01 Oct 2020 12:56:33 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:22', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'c99f245e-2e17-4377-8395-471cf6bf13c3' | System           | 01 Oct 2020 12:56:33 |
| User entered 'No (N)'  | System           | 01 Oct 2020 12:56:33 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:24', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'c99f245e-2e17-4377-8395-471cf6bf13c3' | System           | 01 Oct 2020 12:56:33 |
| User entered 'No (N)'  | System           | 01 Oct 2020 12:56:33 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:27', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'c99f245e-2e17-4377-8395-471cf6bf13c3' | System           | 01 Oct 2020 12:56:33 |
| User entered 'None (1)'  | System           | 01 Oct 2020 12:56:33 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:29', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'c99f245e-2e17-4377-8395-471cf6bf13c3' | System           | 01 Oct 2020 12:56:33 |
| User entered '01 Oct 2020 07:56'   | System           | 01 Oct 2020 12:56:33 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '30 Sep 2020 17:37' | System           | 30 Sep 2020 18:58:02 |



US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '01 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 2' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:30:58', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '89cd1aa7-b3af-46b9-9744-fc05d4b7db02' | System           | 01 Oct 2020 17:31:09 |
| User entered 'None (1)'  | System           | 01 Oct 2020 17:31:09 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:31:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '89cd1aa7-b3af-46b9-9744-fc05d4b7db02' | System           | 01 Oct 2020 17:31:09 |
| User entered 'No (N)'  | System           | 01 Oct 2020 17:31:09 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:31:01', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '89cd1aa7-b3af-46b9-9744-fc05d4b7db02' | System           | 01 Oct 2020 17:31:09 |
| User entered 'No (N)'  | System           | 01 Oct 2020 17:31:09 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:31:03', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '89cd1aa7-b3af-46b9-9744-fc05d4b7db02' | System           | 01 Oct 2020 17:31:09 |
| User entered 'None (1)'  | System           | 01 Oct 2020 17:31:09 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:31:05', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '89cd1aa7-b3af-46b9-9744-fc05d4b7db02' | System           | 01 Oct 2020 17:31:09 |
| User entered '01 Oct 2020 12:31'   | System           | 01 Oct 2020 17:31:09 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '01 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |



US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 3' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

Is there any REDNESS AT INJECTION SITE?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |



US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '03 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 4' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:12:05', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8823a014-4cfc-408e-a9c6-44b8d65e661f' | System           | 03 Oct 2020 23:12:20 |
| User entered 'None (1)'  | System           | 03 Oct 2020 23:12:20 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:12:07', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8823a014-4cfc-408e-a9c6-44b8d65e661f' | System           | 03 Oct 2020 23:12:20 |
| User entered 'No (N)'  | System           | 03 Oct 2020 23:12:20 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:12:09', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8823a014-4cfc-408e-a9c6-44b8d65e661f' | System           | 03 Oct 2020 23:12:20 |
| User entered 'No (N)'  | System           | 03 Oct 2020 23:12:20 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:12:11', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8823a014-4cfc-408e-a9c6-44b8d65e661f' | System           | 03 Oct 2020 23:12:20 |
| User entered 'None (1)'  | System           | 03 Oct 2020 23:12:20 |



US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:12:14', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '8823a014-4cfc-408e-a9c6-44b8d65e661f' | System           | 03 Oct 2020 23:12:20 |
| User entered '03 Oct 2020 18:12'   | System           | 03 Oct 2020 23:12:20 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '03 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '04 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 5' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:01:48', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '85e12da0-864b-44fc-aff7-887455031a2e' | System           | 04 Oct 2020 18:01:59 |
| User entered 'None (1)'  | System           | 04 Oct 2020 18:01:59 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:01:50', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '85e12da0-864b-44fc-aff7-887455031a2e' | System           | 04 Oct 2020 18:01:59 |
| User entered 'No (N)'  | System           | 04 Oct 2020 18:01:59 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:01:51', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '85e12da0-864b-44fc-aff7-887455031a2e' | System           | 04 Oct 2020 18:01:59 |
| User entered 'No (N)'  | System           | 04 Oct 2020 18:01:59 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:01:53', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '85e12da0-864b-44fc-aff7-887455031a2e' | System           | 04 Oct 2020 18:01:59 |
| User entered 'None (1)'  | System           | 04 Oct 2020 18:01:59 |



US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:01:55', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '85e12da0-864b-44fc-aff7-887455031a2e' | System           | 04 Oct 2020 18:01:59 |
| User entered '04 Oct 2020 13:01'   | System           | 04 Oct 2020 18:01:59 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '04 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '05 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 6' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

Is there any REDNESS AT INJECTION SITE?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

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) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |



US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

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) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '05 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '06 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 7' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:52:56', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '55ef7d80-f7bb-4a4b-8c40-10b5550e896b' | System           | 06 Oct 2020 19:53:07 |
| User entered 'None (1)'  | System           | 06 Oct 2020 19:53:07 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:52:59', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '55ef7d80-f7bb-4a4b-8c40-10b5550e896b' | System           | 06 Oct 2020 19:53:07 |
| User entered 'No (N)'  | System           | 06 Oct 2020 19:53:07 |



US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:53:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '55ef7d80-f7bb-4a4b-8c40-10b5550e896b' | System           | 06 Oct 2020 19:53:07 |
| User entered 'No (N)'  | System           | 06 Oct 2020 19:53:07 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

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

Please select one response below

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:53:02', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '55ef7d80-f7bb-4a4b-8c40-10b5550e896b' | System           | 06 Oct 2020 19:53:07 |
| User entered 'None (1)'  | System           | 06 Oct 2020 19:53:07 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:53:04', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '55ef7d80-f7bb-4a4b-8c40-10b5550e896b' | System           | 06 Oct 2020 19:53:07 |
| User entered '06 Oct 2020 14:53'   | System           | 06 Oct 2020 19:53:07 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '06 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '07 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:40', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '761104ad-52aa-472b-8fd8-3da6775e73e3' | System           | 30 Sep 2020 19:22:00 |
| User entered 'None (0)'  | System           | 30 Sep 2020 19:22:00 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:41', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '761104ad-52aa-472b-8fd8-3da6775e73e3' | System           | 30 Sep 2020 19:22:00 |
| User entered 'None (0)'  | System           | 30 Sep 2020 19:22:00 |



US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:43', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '761104ad-52aa-472b-8fd8-3da6775e73e3' | System           | 30 Sep 2020 19:22:00 |
| User entered 'None (0)'  | System           | 30 Sep 2020 19:22:00 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:45', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '761104ad-52aa-472b-8fd8-3da6775e73e3' | System           | 30 Sep 2020 19:22:00 |
| User entered 'None (0)'  | System           | 30 Sep 2020 19:22:00 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:47', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '761104ad-52aa-472b-8fd8-3da6775e73e3' | System           | 30 Sep 2020 19:22:00 |
| User entered 'None (0)'  | System           | 30 Sep 2020 19:22:00 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:49', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '761104ad-52aa-472b-8fd8-3da6775e73e3' | System           | 30 Sep 2020 19:22:00 |
| User entered 'None (0)'  | System           | 30 Sep 2020 19:22:00 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:51', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '761104ad-52aa-472b-8fd8-3da6775e73e3' | System           | 30 Sep 2020 19:22:00 |
| User entered 'No (N)'  | System           | 30 Sep 2020 19:22:00 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-09-30T14:21:53', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '761104ad-52aa-472b-8fd8-3da6775e73e3' | System           | 30 Sep 2020 19:22:00 |
| User entered '30 Sep 2020 14:21'   | System           | 30 Sep 2020 19:22:00 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '30 Sep 2020 14:12' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '30 Sep 2020 16:42' | System           | 30 Sep 2020 18:58:02 |



US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.                                | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 1, after vaccination (at home)' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:32', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e50c6429-b318-43fa-bf5b-878c4b6394af' | System           | 01 Oct 2020 12:56:50 |
| User entered 'None (0)'  | System           | 01 Oct 2020 12:56:50 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:34', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e50c6429-b318-43fa-bf5b-878c4b6394af' | System           | 01 Oct 2020 12:56:50 |
| User entered 'None (0)'  | System           | 01 Oct 2020 12:56:50 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:35', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e50c6429-b318-43fa-bf5b-878c4b6394af' | System           | 01 Oct 2020 12:56:50 |
| User entered 'None (0)'  | System           | 01 Oct 2020 12:56:50 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:36', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e50c6429-b318-43fa-bf5b-878c4b6394af' | System           | 01 Oct 2020 12:56:50 |
| User entered 'None (0)'  | System           | 01 Oct 2020 12:56:50 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:38', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e50c6429-b318-43fa-bf5b-878c4b6394af' | System           | 01 Oct 2020 12:56:50 |
| User entered 'None (0)'  | System           | 01 Oct 2020 12:56:50 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:39', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e50c6429-b318-43fa-bf5b-878c4b6394af' | System           | 01 Oct 2020 12:56:50 |
| User entered 'None (0)'  | System           | 01 Oct 2020 12:56:50 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:43', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e50c6429-b318-43fa-bf5b-878c4b6394af' | System           | 01 Oct 2020 12:56:50 |
| User entered 'No (N)'  | System           | 01 Oct 2020 12:56:50 |



US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T07:56:48', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e50c6429-b318-43fa-bf5b-878c4b6394af' | System           | 01 Oct 2020 12:56:50 |
| User entered '01 Oct 2020 07:56'   | System           | 01 Oct 2020 12:56:50 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '30 Sep 2020 17:37' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '01 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 2' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:31:09', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'fcb2a662-7a65-44da-9d8d-e2c0b33c44ca' | System           | 01 Oct 2020 17:31:26 |
| User entered 'None (0)'  | System           | 01 Oct 2020 17:31:26 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:31:11', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'fcb2a662-7a65-44da-9d8d-e2c0b33c44ca' | System           | 01 Oct 2020 17:31:26 |
| User entered 'None (0)'  | System           | 01 Oct 2020 17:31:26 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:31:12', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'fcb2a662-7a65-44da-9d8d-e2c0b33c44ca' | System           | 01 Oct 2020 17:31:26 |
| User entered 'None (0)'  | System           | 01 Oct 2020 17:31:26 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:31:13', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'fcb2a662-7a65-44da-9d8d-e2c0b33c44ca' | System           | 01 Oct 2020 17:31:26 |
| User entered 'None (0)'  | System           | 01 Oct 2020 17:31:26 |



US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:31:15', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'fcb2a662-7a65-44da-9d8d-e2c0b33c44ca' | System           | 01 Oct 2020 17:31:26 |
| User entered 'None (0)'  | System           | 01 Oct 2020 17:31:26 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:31:16', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'fcb2a662-7a65-44da-9d8d-e2c0b33c44ca' | System           | 01 Oct 2020 17:31:26 |
| User entered 'None (0)'  | System           | 01 Oct 2020 17:31:26 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:31:18', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'fcb2a662-7a65-44da-9d8d-e2c0b33c44ca' | System           | 01 Oct 2020 17:31:26 |
| User entered 'No (N)'  | System           | 01 Oct 2020 17:31:26 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-01T12:31:20', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'fcb2a662-7a65-44da-9d8d-e2c0b33c44ca' | System           | 01 Oct 2020 17:31:26 |
| User entered '01 Oct 2020 12:31'   | System           | 01 Oct 2020 17:31:26 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '01 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 3' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |



US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '02 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |



US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '03 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 4' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:11:30', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cbd41c33-a147-4fe4-b008-075b24043757' | System           | 03 Oct 2020 23:11:46 |
| User entered 'None (0)'  | System           | 03 Oct 2020 23:11:46 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:11:32', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cbd41c33-a147-4fe4-b008-075b24043757' | System           | 03 Oct 2020 23:11:46 |
| User entered 'None (0)'  | System           | 03 Oct 2020 23:11:46 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:11:33', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cbd41c33-a147-4fe4-b008-075b24043757' | System           | 03 Oct 2020 23:11:46 |
| User entered 'None (0)'  | System           | 03 Oct 2020 23:11:46 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:11:34', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cbd41c33-a147-4fe4-b008-075b24043757' | System           | 03 Oct 2020 23:11:46 |
| User entered 'None (0)'  | System           | 03 Oct 2020 23:11:46 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:11:36', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cbd41c33-a147-4fe4-b008-075b24043757' | System           | 03 Oct 2020 23:11:46 |
| User entered 'None (0)'  | System           | 03 Oct 2020 23:11:46 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:11:38', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cbd41c33-a147-4fe4-b008-075b24043757' | System           | 03 Oct 2020 23:11:46 |
| User entered 'None (0)'  | System           | 03 Oct 2020 23:11:46 |



US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:11:40', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cbd41c33-a147-4fe4-b008-075b24043757' | System           | 03 Oct 2020 23:11:46 |
| User entered 'No (N)'  | System           | 03 Oct 2020 23:11:46 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-03T18:11:42', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'cbd41c33-a147-4fe4-b008-075b24043757' | System           | 03 Oct 2020 23:11:46 |
| User entered '03 Oct 2020 18:11'   | System           | 03 Oct 2020 23:11:46 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '03 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '04 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 5' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:01:59', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5f7e1e1d-5acb-4496-be1e-5e3ad9cc6389' | System           | 04 Oct 2020 18:02:13 |
| User entered 'None (0)'  | System           | 04 Oct 2020 18:02:13 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:02:01', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5f7e1e1d-5acb-4496-be1e-5e3ad9cc6389' | System           | 04 Oct 2020 18:02:13 |
| User entered 'None (0)'  | System           | 04 Oct 2020 18:02:13 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:02:02', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5f7e1e1d-5acb-4496-be1e-5e3ad9cc6389' | System           | 04 Oct 2020 18:02:13 |
| User entered 'None (0)'  | System           | 04 Oct 2020 18:02:13 |



US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:02:03', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5f7e1e1d-5acb-4496-be1e-5e3ad9cc6389' | System           | 04 Oct 2020 18:02:13 |
| User entered 'None (0)'  | System           | 04 Oct 2020 18:02:13 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:02:04', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5f7e1e1d-5acb-4496-be1e-5e3ad9cc6389' | System           | 04 Oct 2020 18:02:13 |
| User entered 'None (0)'  | System           | 04 Oct 2020 18:02:13 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:02:05', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5f7e1e1d-5acb-4496-be1e-5e3ad9cc6389' | System           | 04 Oct 2020 18:02:13 |
| User entered 'None (0)'  | System           | 04 Oct 2020 18:02:13 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:02:07', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5f7e1e1d-5acb-4496-be1e-5e3ad9cc6389' | System           | 04 Oct 2020 18:02:13 |
| User entered 'No (N)'  | System           | 04 Oct 2020 18:02:13 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-04T13:02:09', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5f7e1e1d-5acb-4496-be1e-5e3ad9cc6389' | System           | 04 Oct 2020 18:02:13 |
| User entered '04 Oct 2020 13:02'   | System           | 04 Oct 2020 18:02:13 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '04 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '05 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 6' | System           | 30 Sep 2020 18:58:02 |



US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
|                   |                  |                      |



US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '05 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '06 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.   | System           | 30 Sep 2020 18:58:02 |
| User entered 'Day 7' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:53:08', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'b6bb71e3-9246-469a-86d3-aed545fd05b3' | System           | 06 Oct 2020 19:53:25 |
| User entered 'None (0)'  | System           | 06 Oct 2020 19:53:25 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:53:10', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'b6bb71e3-9246-469a-86d3-aed545fd05b3' | System           | 06 Oct 2020 19:53:25 |
| User entered 'None (0)'  | System           | 06 Oct 2020 19:53:25 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:53:11', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'b6bb71e3-9246-469a-86d3-aed545fd05b3' | System           | 06 Oct 2020 19:53:25 |
| User entered 'None (0)'  | System           | 06 Oct 2020 19:53:25 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:53:14', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'b6bb71e3-9246-469a-86d3-aed545fd05b3' | System           | 06 Oct 2020 19:53:25 |
| User entered 'None (0)'  | System           | 06 Oct 2020 19:53:25 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:53:15', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'b6bb71e3-9246-469a-86d3-aed545fd05b3' | System           | 06 Oct 2020 19:53:25 |
| User entered 'None (0)'  | System           | 06 Oct 2020 19:53:25 |



US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:53:17', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'b6bb71e3-9246-469a-86d3-aed545fd05b3' | System           | 06 Oct 2020 19:53:25 |
| User entered 'None (0)'  | System           | 06 Oct 2020 19:53:25 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:53:20', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'b6bb71e3-9246-469a-86d3-aed545fd05b3' | System           | 06 Oct 2020 19:53:25 |
| User entered 'No (N)'  | System           | 06 Oct 2020 19:53:25 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-10-06T14:53:22', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'b6bb71e3-9246-469a-86d3-aed545fd05b3' | System           | 06 Oct 2020 19:53:25 |
| User entered '06 Oct 2020 14:53'   | System           | 06 Oct 2020 19:53:25 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '06 Oct 2020 12:00' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:03:25

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| User entered '07 Oct 2020 11:59' | System           | 30 Sep 2020 18:58:02 |

US3312465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Oct 2020 21:37:07 |

US3312465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '7 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 08 Oct 2020 21:37:07 |

US3312465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.                  | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 08 Oct 2020 21:37:07 |



US3312465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 08 Oct 2020 21:37:07 |

US3312465

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Oct 2020 21:36:53 |

US3312465

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'I'  | System           | 08 Oct 2020 21:36:53 |

US3312465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Was Contact Attempted?](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4) | 17 Oct 2020 21:33:00 |

US3312465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)               | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered '15 Oct 2020' | (b) (4)<br>Karol Moore (b) (4) | 17 Oct 2020 21:33:00 |

US3312465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                      | Time (GMT)           |
|--|---|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                          | 28 Apr 2021 18:38:58 |
| User signature succeeded.                  | Carlos Fierro (b) (4)                     | 15 Feb 2021 22:50:13 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:33:00 |

US3312465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4) | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)               | 17 Oct 2020 21:33:00 |
|                           | Karol Moore (b) (4)   |                      |
|                           | (b) (4)               |                      |

US3312465

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4) | 17 Oct 2020 21:33:04 |



US3312465

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'I'  | System           | 17 Oct 2020 21:33:04 |

US3312465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Oct 2020 15:12:47 |

US3312465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '22 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 23 Oct 2020 15:12:47 |

US3312465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.                  | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 23 Oct 2020 15:12:47 |

US3312465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 23 Oct 2020 15:12:47 |

US3312465

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 23 Oct 2020 15:12:58 |

US3312465

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'I'  | System           | 23 Oct 2020 15:12:58 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:27:46 |



US3312465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '28 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:27:46 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.      | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:27:46 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'VISIT3' | System           | 29 Oct 2020 20:27:46 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:15 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '28 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:15 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Time of assessment (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '12:47'      | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:15 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered '28 Oct 2020 12:47' | System           | 29 Oct 2020 20:28:15 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '98.0' F     | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:15 |



US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:15 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:15 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '86'         | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:15 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'bpm' | System           | 29 Oct 2020 20:28:15 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '16'         | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:15 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'breaths/min' | System           | 29 Oct 2020 20:28:15 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Systolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '121'        | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:15 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'mmHg' | System           | 29 Oct 2020 20:28:15 |



US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '76'         | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:15 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'mmHg' | System           | 29 Oct 2020 20:28:15 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Height (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
|                   |                  |                      |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:25

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:21 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:25

Date of examination (dd MMM yyyy)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:21 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:32 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

Collection date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '28 Oct 2020' | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:32 |



US3312465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

Collection time (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered '13:03'      | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:32 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered '28 Oct 2020 13:03' | System           | 29 Oct 2020 20:28:32 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 15 Feb 2021 22:50:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 29 Oct 2020 20:28:36 |

US3312465

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'I'  | System           | 29 Oct 2020 20:28:36 |

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.    | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 64' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-11-05T18:04:06', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '46b64eb4-aeb2-4c96-b469-937bfedf6da0' | System           | 06 Nov 2020 00:04:13 |
| User entered 'No (N)'  | System           | 06 Nov 2020 00:04:13 |

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-11-05T18:04:08', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '46b64eb4-aeb2-4c96-b469-937bfedf6da0' | System           | 06 Nov 2020 00:04:13 |
| User entered 'No (N)'  | System           | 06 Nov 2020 00:04:13 |

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-11-05T18:04:10', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '46b64eb4-aeb2-4c96-b469-937bfedf6da0' | System           | 06 Nov 2020 00:04:13 |
| User entered '05 Nov 2020 18:04:10'  | System           | 06 Nov 2020 00:04:13 |



US3312465

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.               | System           | 02 Sep 2020 20:35:37 |
| User entered '02 Nov 2020 00:01' | System           | 02 Sep 2020 20:35:37 |

US3312465

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.               | System           | 02 Sep 2020 20:35:37 |
| User entered '06 Nov 2020 23:59' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.    | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 71' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-11-09T22:03:36', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '0af75ce5-ebfd-4d89-8838-9123afc88903' | System           | 10 Nov 2020 04:03:43 |
| User entered 'No (N)'  | System           | 10 Nov 2020 04:03:43 |

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-11-09T22:03:38', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '0af75ce5-ebfd-4d89-8838-9123afc88903' | System           | 10 Nov 2020 04:03:43 |
| User entered 'No (N)'  | System           | 10 Nov 2020 04:03:43 |

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-11-09T22:03:40', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '0af75ce5-ebfd-4d89-8838-9123afc88903' | System           | 10 Nov 2020 04:03:43 |
| User entered '09 Nov 2020 22:03:40'  | System           | 10 Nov 2020 04:03:43 |

US3312465

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.               | System           | 02 Sep 2020 20:35:37 |
| User entered '09 Nov 2020 00:01' | System           | 02 Sep 2020 20:35:37 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.               | System           | 02 Sep 2020 20:35:37 |
| User entered '13 Nov 2020 23:59' | System           | 02 Sep 2020 20:35:37 |



US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.    | System           | 02 Sep 2020 20:35:37 |
| User entered 'Day 78' | System           | 02 Sep 2020 20:35:37 |

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-11-17T02:24:48', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '23a6a0dc-d2db-4d56-9394-e45e47aef7ee' | System           | 17 Nov 2020 08:24:55 |
| User entered 'No (N)'  | System           | 17 Nov 2020 08:24:55 |

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-11-17T02:24:50', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '23a6a0dc-d2db-4d56-9394-e45e47aef7ee' | System           | 17 Nov 2020 08:24:55 |
| User entered 'No (N)'  | System           | 17 Nov 2020 08:24:55 |

US3312465

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

[Date and time of submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-11-17T02:24:51', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '23a6a0dc-d2db-4d56-9394-e45e47aef7ee' | System           | 17 Nov 2020 08:24:55 |
| User entered '17 Nov 2020 02:24:51'  | System           | 17 Nov 2020 08:24:55 |

US3312465

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.               | System           | 02 Sep 2020 20:35:37 |
| User entered '16 Nov 2020 00:01' | System           | 02 Sep 2020 20:35:37 |

US3312465

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 23:46:25 |
| Data entry locked.               | System           | 02 Sep 2020 20:35:37 |
| User entered '20 Nov 2020 23:59' | System           | 02 Sep 2020 20:35:37 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 82' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '20 Nov 2020 00:01' | System | 20 Nov 2020 02:53:20 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '24 Nov 2020 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 89' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '27 Nov 2020 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '01 Dec 2020 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 96' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (ee30ec48e4e6e028)', Time: '2020-12-08T12:23:28', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '2a09118e-8105-415f-811b-3f81437f77c7' | System | 08 Dec 2020 18:23:37 |
| User entered 'No (N)'  | System | 08 Dec 2020 18:23:37 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Have you been exposed to someone with 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 (ee30ec48e4e6e028)', Time: '2020-12-08T12:23:29', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '2a09118e-8105-415f-811b-3f81437f77c7' | System | 08 Dec 2020 18:23:37 |
| User entered 'No (N)'  | System | 08 Dec 2020 18:23:37 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-12-08T12:23:31', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '2a09118e-8105-415f-811b-3f81437f77c7' | System | 08 Dec 2020 18:23:37 |
| User entered '08 Dec 2020 12:23:31'  | System | 08 Dec 2020 18:23:37 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '04 Dec 2020 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '08 Dec 2020 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 103' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (ee30ec48e4e6e028)', Time: '2020-12-14T15:25:26', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'b9122fed-dbc0-420c-92dc-687a46715670' | System | 14 Dec 2020 21:25:37 |
| User entered 'No (N)'  | System | 14 Dec 2020 21:25:37 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

Have you been exposed to someone with 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 (ee30ec48e4e6e028)', Time: '2020-12-14T15:25:30', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'b9122fed-dbc0-420c-92dc-687a46715670' | System | 14 Dec 2020 21:25:37 |
| User entered 'No (N)'  | System | 14 Dec 2020 21:25:37 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-12-14T15:25:33', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'b9122fed-dbc0-420c-92dc-687a46715670' User entered '14 Dec 2020 15:25:33' | System | 14 Dec 2020 21:25:37 |
|  | System | 14 Dec 2020 21:25:37 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '11 Dec 2020 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '15 Dec 2020 23:59' | System | 20 Nov 2020 02:53:20 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 110' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '18 Dec 2020 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '22 Dec 2020 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 117' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (ee30ec48e4e6e028)', Time: '2020-12-29T17:38:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '9b5ae749-3889-4275-8735-1f2ee004f406' | System | 29 Dec 2020 23:38:10 |
| User entered 'No (N)'  | System | 29 Dec 2020 23:38:10 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Have you been exposed to someone with 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 (ee30ec48e4e6e028)', Time: '2020-12-29T17:38:02', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '9b5ae749-3889-4275-8735-1f2ee004f406' | System | 29 Dec 2020 23:38:10 |
| User entered 'No (N)'  | System | 29 Dec 2020 23:38:10 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee30ec48e4e6e028)', Time: '2020-12-29T17:38:04', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '9b5ae749-3889-4275-8735-1f2ee004f406' | System | 29 Dec 2020 23:38:10 |
| User entered '29 Dec 2020 17:38:04'  | System | 29 Dec 2020 23:38:10 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '25 Dec 2020 00:01' | System | 20 Nov 2020 02:53:20 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '29 Dec 2020 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 124' | System | 20 Nov 2020 02:53:20 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-05T08:21:39', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '4c2d684b-6d41-40db-bc74-a4a815aec939' | System | 05 Jan 2021 14:21:58 |
| User entered 'No (N)'  | System | 05 Jan 2021 14:21:58 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-05T08:21:47', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '4c2d684b-6d41-40db-bc74-a4a815aec939' | System | 05 Jan 2021 14:21:58 |
| User entered 'No (N)'  | System | 05 Jan 2021 14:21:58 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-05T08:21:49', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '4c2d684b-6d41-40db-bc74-a4a815aec939' User entered '05 Jan 2021 08:21:49' | System | 05 Jan 2021 14:21:58 |
|  | System | 05 Jan 2021 14:21:58 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '01 Jan 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '05 Jan 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 131' | System | 20 Nov 2020 02:53:20 |



US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-12T12:16:12', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '66bbb1f5-4a51-46e3-8d02-42e045d7b2aa' User entered 'No (N)' | System | 12 Jan 2021 18:16:22 |
|  | System | 12 Jan 2021 18:16:22 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-12T12:16:15', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '66bbb1f5-4a51-46e3-8d02-42e045d7b2aa' | System | 12 Jan 2021 18:16:22 |
| User entered 'No (N)'  | System | 12 Jan 2021 18:16:22 |

**US3312465**

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

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**Generated On: 09 Jun 2021 17:03:25**

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| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-12T12:16:18', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '66bbb1f5-4a51-46e3-8d02-42e045d7b2aa' User entered '12 Jan 2021 12:16:18' | System | 12 Jan 2021 18:16:22 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '08 Jan 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '12 Jan 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 138' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-15T11:29:20', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e33f35b4-9822-4a6b-ad38-3bc0fc604b3d' User entered 'No (N)' | System | 15 Jan 2021 17:29:27 |
|  | System | 15 Jan 2021 17:29:27 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-15T11:29:22', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e33f35b4-9822-4a6b-ad38-3bc0fc604b3d' User entered 'No (N)' | System | 15 Jan 2021 17:29:27 |
|  | System | 15 Jan 2021 17:29:27 |



**US3312465**

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

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**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-15T11:29:24', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e33f35b4-9822-4a6b-ad38-3bc0fc604b3d' User entered '15 Jan 2021 11:29:24' | System | 15 Jan 2021 17:29:27 |
|  | System | 15 Jan 2021 17:29:27 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '15 Jan 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '19 Jan 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 145' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-22T05:25:25', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5e09a6d4-37d9-46db-8790-7c8fcda94535' User entered 'No (N)' | System | 22 Jan 2021 11:25:42 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-22T05:25:34', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5e09a6d4-37d9-46db-8790-7c8fcda94535' | System | 22 Jan 2021 11:25:42 |
| User entered 'No (N)'  | System | 22 Jan 2021 11:25:42 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-22T05:25:37', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5e09a6d4-37d9-46db-8790-7c8fcda94535' User entered '22 Jan 2021 05:25:37' | System | 22 Jan 2021 11:25:42 |
|  | System | 22 Jan 2021 11:25:42 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '22 Jan 2021 00:01' | System | 20 Nov 2020 02:53:20 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '26 Jan 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 152' | System | 20 Nov 2020 02:53:20 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-30T08:26:09', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '44d152f5-a74a-4d6b-a21a-5160d7f9c32d' User entered 'No (N)' | System | 30 Jan 2021 14:26:16 |
|  | System | 30 Jan 2021 14:26:16 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-30T08:26:12', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '44d152f5-a74a-4d6b-a21a-5160d7f9c32d' User entered 'No (N)' | System | 30 Jan 2021 14:26:16 |
|  | System | 30 Jan 2021 14:26:16 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-01-30T08:26:15', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '44d152f5-a74a-4d6b-a21a-5160d7f9c32d' User entered '30 Jan 2021 08:26:15' | System | 30 Jan 2021 14:26:16 |
|  | System | 30 Jan 2021 14:26:16 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '29 Jan 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '02 Feb 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 159' | System | 20 Nov 2020 02:53:20 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-05T05:20:34', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '75d6db8f-879b-4c81-8afd-4e078c8cb5fd' User entered 'No (N)' | System | 05 Feb 2021 11:20:43 |
|  | System | 05 Feb 2021 11:20:43 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-05T05:20:35', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '75d6db8f-879b-4c81-8afd-4e078c8cb5fd' | System | 05 Feb 2021 11:20:43 |
| User entered 'No (N)'  | System | 05 Feb 2021 11:20:43 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-05T05:20:37', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '75d6db8f-879b-4c81-8afd-4e078c8cb5fd' User entered '05 Feb 2021 05:20:37' | System | 05 Feb 2021 11:20:43 |
|  | System | 05 Feb 2021 11:20:43 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '05 Feb 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '09 Feb 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 166' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-12T00:35:14', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '81c340da-a12e-4000-8c43-dfd50c72c4ee' User entered 'No (N)' | System | 12 Feb 2021 06:35:24 |
|  | System | 12 Feb 2021 06:35:24 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-12T00:35:16', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '81c340da-a12e-4000-8c43-dfd50c72c4ee' User entered 'No (N)' | System | 12 Feb 2021 06:35:24 |
|  | System | 12 Feb 2021 06:35:24 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-12T00:35:19', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '81c340da-a12e-4000-8c43-dfd50c72c4ee' User entered '12 Feb 2021 00:35:19' | System | 12 Feb 2021 06:35:24 |
|  | System | 12 Feb 2021 06:35:24 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '12 Feb 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '16 Feb 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 173' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-20T12:02:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5842a5ad-b31c-4ed2-a238-2ae94613dcfe' User entered 'No (N)' | System | 22 Feb 2021 21:06:25 |
|  | System | 22 Feb 2021 21:06:25 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-20T12:02:01', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5842a5ad-b31c-4ed2-a238-2ae94613dcfe' User entered 'No (N)' | System | 22 Feb 2021 21:06:25 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-20T12:02:08', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '5842a5ad-b31c-4ed2-a238-2ae94613dcfe' User entered '20 Feb 2021 12:02:08' | System | 22 Feb 2021 21:06:25 |
|  | System | 22 Feb 2021 21:06:25 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '19 Feb 2021 00:01' | System | 20 Nov 2020 02:53:20 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '23 Feb 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 180' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-27T12:52:12', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '2011793f-119f-4f37-a72c-c0af999ec552' User entered 'No (N)' | System | 27 Feb 2021 18:52:18 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-27T12:52:13', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '2011793f-119f-4f37-a72c-c0af999ec552' | System | 27 Feb 2021 18:52:18 |
| User entered 'No (N)'  | System | 27 Feb 2021 18:52:18 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-27T12:52:16', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '2011793f-119f-4f37-a72c-c0af999ec552' | System | 27 Feb 2021 18:52:18 |
| User entered '27 Feb 2021 12:52:16'  | System | 27 Feb 2021 18:52:18 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '26 Feb 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '02 Mar 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 187' | System | 20 Nov 2020 02:53:20 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-03-05T20:52:47-06:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd4b21c18-1632-4b97-89f0-9e4daf4162c9' | System | 06 Mar 2021 03:16:59 |
| User entered 'No (N)'  | System | 06 Mar 2021 03:16:59 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-03-05T20:52:48-06:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd4b21c18-1632-4b97-89f0-9e4daf4162c9' User entered 'No (N)' | System | 06 Mar 2021 03:16:59 |
|  | System | 06 Mar 2021 03:16:59 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-03-05T20:52:51-06:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'd4b21c18-1632-4b97-89f0-9e4daf4162c9' | System | 06 Mar 2021 03:16:59 |
| User entered '05 Mar 2021 20:52:51'  | System | 06 Mar 2021 03:16:59 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '05 Mar 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '09 Mar 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 194' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-03-15T14:57:48-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'a500ba61-3a95-4164-ae1e-e9ea3a3e8cb7' | System | 15 Mar 2021 19:57:54 |
| User entered 'No (N)'  | System | 15 Mar 2021 19:57:54 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-03-15T14:57:49-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'a500ba61-3a95-4164-ae1e-e9ea3a3e8cb7' | System | 15 Mar 2021 19:57:54 |
| User entered 'No (N)'  | System | 15 Mar 2021 19:57:54 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-03-15T14:57:51-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'a500ba61-3a95-4164-ae1e-e9ea3a3e8cb7' User entered '15 Mar 2021 14:57:51' | System | 15 Mar 2021 19:57:54 |
|  | System | 15 Mar 2021 19:57:54 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '12 Mar 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '16 Mar 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 201' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-03-20T08:43:28-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'a1f8a847-9f59-4a65-b918-fd369ef7d9aa' | System | 20 Mar 2021 13:43:34 |
| User entered 'No (N)'  | System | 20 Mar 2021 13:43:34 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-03-20T08:43:29-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'a1f8a847-9f59-4a65-b918-fd369ef7d9aa' | System | 20 Mar 2021 13:43:34 |
| User entered 'No (N)'  | System | 20 Mar 2021 13:43:34 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-03-20T08:43:31-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'a1f8a847-9f59-4a65-b918-fd369ef7d9aa' User entered '20 Mar 2021 08:43:31' | System | 20 Mar 2021 13:43:34 |
|  | System | 20 Mar 2021 13:43:34 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '19 Mar 2021 00:01' | System | 20 Nov 2020 02:53:20 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '23 Mar 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 208' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-03-26T09:23:49-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '84b3f435-129d-4fe0-af5c-08226c815d54' | System | 26 Mar 2021 14:23:56 |
| User entered 'No (N)'  | System | 26 Mar 2021 14:23:56 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-03-26T09:23:50-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '84b3f435-129d-4fe0-af5c-08226c815d54' | System | 26 Mar 2021 14:23:56 |
| User entered 'No (N)'  | System | 26 Mar 2021 14:23:56 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-03-26T09:23:52-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '84b3f435-129d-4fe0-af5c-08226c815d54' User entered '26 Mar 2021 09:23:52' | System | 26 Mar 2021 14:23:56 |
|  | System | 26 Mar 2021 14:23:56 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '26 Mar 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '30 Mar 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 215' | System | 20 Nov 2020 02:53:20 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-04-02T00:02:25-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1de03248-6d02-4d2a-9deb-aab12fbd50c0' User entered 'No (N)' | System | 02 Apr 2021 05:02:41 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-04-02T00:02:29-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1de03248-6d02-4d2a-9deb-aab12fbd50c0' User entered 'No (N)' | System | 02 Apr 2021 05:02:41 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-04-02T00:02:31-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1de03248-6d02-4d2a-9deb-aab12fbd50c0' User entered '02 Apr 2021 00:02:31' | System | 02 Apr 2021 05:02:41 |
|  | System | 02 Apr 2021 05:02:41 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '02 Apr 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '06 Apr 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 222' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-04-11T12:00:12-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'bd8aeaaa-f93e-4094-9792-a951cc7b33dd' | System | 11 Apr 2021 17:00:19 |
| User entered 'No (N)'  | System | 11 Apr 2021 17:00:19 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-04-11T12:00:13-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'bd8aeaaa-f93e-4094-9792-a951cc7b33dd' | System | 11 Apr 2021 17:00:19 |
| User entered 'No (N)'  | System | 11 Apr 2021 17:00:19 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-04-11T12:00:15-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'bd8aeaaa-f93e-4094-9792-a951cc7b33dd' | System | 11 Apr 2021 17:00:19 |
| User entered '11 Apr 2021 12:00:15'  | System | 11 Apr 2021 17:00:19 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '09 Apr 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '13 Apr 2021 23:59' | System | 20 Nov 2020 02:53:20 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 229' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-04-18T13:21:15-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '61986468-b4fe-4cc8-a6f0-c9b5dc39e2a7' | System | 18 Apr 2021 18:21:23 |
| User entered 'No (N)'  | System | 18 Apr 2021 18:21:23 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-04-18T13:21:17-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '61986468-b4fe-4cc8-a6f0-c9b5dc39e2a7' User entered 'No (N)' | System | 18 Apr 2021 18:21:23 |
|  | System | 18 Apr 2021 18:21:23 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-04-18T13:21:19-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '61986468-b4fe-4cc8-a6f0-c9b5dc39e2a7' | System | 18 Apr 2021 18:21:23 |
| User entered '18 Apr 2021 13:21:19'  | System | 18 Apr 2021 18:21:23 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '16 Apr 2021 00:01' | System | 20 Nov 2020 02:53:20 |



**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '20 Apr 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 236' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-04-23T00:05:23-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '533383ab-a657-4a13-9a56-152b8d7e0eea' User entered 'No (N)' | System | 23 Apr 2021 05:05:32 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-04-23T00:05:25-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '533383ab-a657-4a13-9a56-152b8d7e0eea' User entered 'No (N)' | System | 23 Apr 2021 05:05:32 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-04-23T00:05:28-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '533383ab-a657-4a13-9a56-152b8d7e0eea' User entered '23 Apr 2021 00:05:28' | System | 23 Apr 2021 05:05:32 |
|  | System | 23 Apr 2021 05:05:32 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '23 Apr 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '27 Apr 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 243' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-05-02T12:00:41-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e6e36f94-ab1d-4768-bff7-e150dbd6bcf5' | System | 02 May 2021 17:01:10 |
| User entered 'No (N)'  | System | 02 May 2021 17:01:10 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Have you been exposed to someone with 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 (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-05-02T12:00:42-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e6e36f94-ab1d-4768-bff7-e150dbd6bcf5' | System | 02 May 2021 17:01:10 |
| User entered 'No (N)'  | System | 02 May 2021 17:01:10 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-05-02T12:00:44-05:00', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: 'e6e36f94-ab1d-4768-bff7-e150dbd6bcf5' | System | 02 May 2021 17:01:10 |
| User entered '02 May 2021 12:00:44'  | System | 02 May 2021 17:01:10 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '30 Apr 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '04 May 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 250' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '07 May 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '11 May 2021 23:59' | System | 20 Nov 2020 02:53:20 |



**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 257' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '14 May 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '18 May 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 264' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '21 May 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '25 May 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 271' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '28 May 2021 00:01' | System | 20 Nov 2020 02:53:20 |



**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '01 Jun 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 278' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '04 Jun 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '08 Jun 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 285' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '11 Jun 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '15 Jun 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 292' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '18 Jun 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '22 Jun 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 299' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '25 Jun 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '29 Jun 2021 23:59' | System | 20 Nov 2020 02:53:20 |

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Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 306' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '02 Jul 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '06 Jul 2021 23:59' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 313' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '09 Jul 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '13 Jul 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 320' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '16 Jul 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '20 Jul 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 327' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '23 Jul 2021 00:01' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '27 Jul 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 334' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '30 Jul 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '03 Aug 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 341' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '06 Aug 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '10 Aug 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 348' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '13 Aug 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '17 Aug 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 355' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '20 Aug 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '24 Aug 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 362' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '27 Aug 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '31 Aug 2021 23:59' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 369' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '03 Sep 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '07 Sep 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 376' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '10 Sep 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '14 Sep 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 383' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '17 Sep 2021 00:01' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '21 Sep 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 390' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '24 Sep 2021 00:01' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '28 Sep 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 397' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '01 Oct 2021 00:01' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '05 Oct 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 404' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '08 Oct 2021 00:01' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '12 Oct 2021 23:59' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 411' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '15 Oct 2021 00:01' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '19 Oct 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 418' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '22 Oct 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '26 Oct 2021 23:59' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 425' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '29 Oct 2021 00:01' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '02 Nov 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 432' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '05 Nov 2021 00:01' | System | 20 Nov 2020 02:53:20 |

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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 02:53:20 |
| Amendment Manager: User entered '09 Nov 2021 23:59' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 439' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '12 Nov 2021 00:01' | System | 20 Nov 2020 02:53:20 |



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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 02:53:20 |
| Amendment Manager: User entered '16 Nov 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 446' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '19 Nov 2021 00:01' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '23 Nov 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 453' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '26 Nov 2021 00:01' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '30 Nov 2021 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 460' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '03 Dec 2021 00:01' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '07 Dec 2021 23:59' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 467' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '10 Dec 2021 00:01' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '14 Dec 2021 23:59' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 474' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '17 Dec 2021 00:01' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '21 Dec 2021 23:59' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 481' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '24 Dec 2021 00:01' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '28 Dec 2021 23:59' | System | 20 Nov 2020 02:53:20 |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 488' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '31 Dec 2021 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '04 Jan 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**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 02:53:20 |
| Amendment Manager: User entered 'Day 495' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '07 Jan 2022 00:01' | System | 20 Nov 2020 02:53:20 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '11 Jan 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 502' | System | 20 Nov 2020 02:53:20 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '14 Jan 2022 00:01' | System | 20 Nov 2020 02:53:20 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '18 Jan 2022 23:59' | System | 20 Nov 2020 02:53:20 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 509' | System | 20 Nov 2020 02:53:20 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '21 Jan 2022 00:01' | System | 20 Nov 2020 02:53:20 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '25 Jan 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 516' | System | 20 Nov 2020 02:53:20 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '28 Jan 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '01 Feb 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 523' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '04 Feb 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '08 Feb 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 530' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '11 Feb 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '15 Feb 2022 23:59' | System | 20 Nov 2020 02:53:20 |



**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 537' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '18 Feb 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '22 Feb 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 544' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '25 Feb 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '01 Mar 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 551' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '04 Mar 2022 00:01' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '08 Mar 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 558' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '11 Mar 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '15 Mar 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 565' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '18 Mar 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '22 Mar 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 572' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '25 Mar 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '29 Mar 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 579' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '01 Apr 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '05 Apr 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 586' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '08 Apr 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '12 Apr 2022 23:59' | System | 20 Nov 2020 02:53:20 |



**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 593' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '15 Apr 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '19 Apr 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 600' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '22 Apr 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '26 Apr 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 607' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '29 Apr 2022 00:01' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '03 May 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 614' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '06 May 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '10 May 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 621' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '13 May 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '17 May 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 628' | System | 20 Nov 2020 02:53:20 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '20 May 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '24 May 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 635' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '27 May 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**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 02:53:20 |
| Amendment Manager: User entered '31 May 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 642' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '03 Jun 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '07 Jun 2022 23:59' | System | 20 Nov 2020 02:53:20 |



**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 649' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '10 Jun 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '14 Jun 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 656' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '17 Jun 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '21 Jun 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 663' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '24 Jun 2022 00:01' | System | 20 Nov 2020 02:53:20 |



**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '28 Jun 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 670' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '01 Jul 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '05 Jul 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 677' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '08 Jul 2022 00:01' | System | 20 Nov 2020 02:53:20 |

US3312465

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '12 Jul 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 684' | System | 20 Nov 2020 02:53:20 |



**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '15 Jul 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '19 Jul 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 691' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '22 Jul 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '26 Jul 2022 23:59' | System | 20 Nov 2020 02:53:20 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 698' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '29 Jul 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '02 Aug 2022 23:59' | System | 20 Nov 2020 02:53:20 |



**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 705' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '05 Aug 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '09 Aug 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 712' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '12 Aug 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '16 Aug 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 719' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '19 Aug 2022 00:01' | System | 20 Nov 2020 02:53:20 |



**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '23 Aug 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 726' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '26 Aug 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '30 Aug 2022 23:59' | System | 20 Nov 2020 02:53:20 |

US3312465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:03:25

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 733' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '02 Sep 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '06 Sep 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 740' | System | 20 Nov 2020 02:53:20 |



**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '09 Sep 2022 00:01' | System | 20 Nov 2020 02:53:20 |

US3312465

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '13 Sep 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 747' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '16 Sep 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '20 Sep 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 754' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '23 Sep 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '27 Sep 2022 23:59' | System | 20 Nov 2020 02:53:20 |



**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 761' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '30 Sep 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '04 Oct 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 768' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '07 Oct 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '11 Oct 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 775' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '14 Oct 2022 00:01' | System | 20 Nov 2020 02:53:20 |



**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '18 Oct 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 782' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '21 Oct 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '25 Oct 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 789' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '28 Oct 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '01 Nov 2022 23:59' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered 'Day 796' | System | 20 Nov 2020 02:53:20 |



**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '04 Nov 2022 00:01' | System | 20 Nov 2020 02:53:20 |

**US3312465**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:03:25**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 20 Nov 2020 02:53:20 |
| Amendment Manager: User entered '08 Nov 2022 23:59' | System | 20 Nov 2020 02:53:20 |

US3312465

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:03:25**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Apr 2021 17:17:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-27T12:52:19', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1258c07e-dc35-4974-80be-f650b0bd2318' User entered 'Yes (Y)' | System           | 27 Feb 2021 18:52:34 |
|   | System           | 27 Feb 2021 18:52:34 |

US3312465

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:03:25**

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) | 25 Apr 2021 17:17:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-27T12:52:21', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1258c07e-dc35-4974-80be-f650b0bd2318' User entered 'Yes (Y)' | System           | 27 Feb 2021 18:52:34 |
|   | System           | 27 Feb 2021 18:52:34 |

**US3312465**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Date & Time of Submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 17:17:49 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (117E0CEB-1D35-44D5-BA37-1561F0870C76)', Time: '2021-02-27T12:52:23', User OID: 'PatientReportedOutcome (US3312465)', ODM File OID: '1258c07e-dc35-4974-80be-f650b0bd2318' User entered '27 Feb 2021 12:52:23' | System           | 27 Feb 2021 18:52:34 |
|  | System           | 27 Feb 2021 18:52:34 |

US3312465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 15:23:47 |

US3312465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '25 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 15:23:47 |

US3312465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded.                  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 15:23:47 |



US3312465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 15:23:47 |

US3312465

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:38:58 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 30 Nov 2020 15:26:31 |

US3312465

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:38:58 |
| User entered 'I'  | System           | 30 Nov 2020 15:26:31 |

US3312465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 30 Dec 2020 15:45:02 |

US3312465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '29 Dec 2020' | (b) (4)<br>(b) (4), (b) (6) | 30 Dec 2020 15:45:02 |

US3312465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded.                  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 30 Dec 2020 15:45:02 |

US3312465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 30 Dec 2020 15:45:02 |

US3312465

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 30 Dec 2020 15:44:43 |



US3312465

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 08:06:54 |
| User entered 'I'  | System           | 30 Dec 2020 15:44:43 |

US3312465

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 16:47:22 |

US3312465

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '27 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 16:47:22 |

US3312465

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded.                  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 16:47:22 |

US3312465

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 16:47:22 |

US3312465

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 28 Jan 2021 16:47:27 |

US3312465

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 08:06:54 |
| User entered 'I'  | System           | 28 Jan 2021 16:47:27 |

US3312465

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:15:03 |



US3312465

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '25 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:15:03 |

US3312465

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded.                  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:15:03 |

US3312465

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:03:25

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:15:03 |

US3312465

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:14:51 |

US3312465

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 08:06:54 |
| User entered 'I'  | System           | 01 Mar 2021 14:14:51 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Was this visit performed?](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4) | 30 Mar 2021 13:49:13 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)               | 14 Apr 2021 08:06:54 |
| User signature succeeded.  | Carlos Fierro (b) (4)          | 06 Apr 2021 02:47:03 |
| User entered '26 Mar 2021' | (b) (4)<br>Karol Moore (b) (4) | 30 Mar 2021 13:49:13 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                           | Time (GMT)           |
|--------------------------------|--------------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)               | 14 Apr 2021 08:06:54 |
| User signature succeeded.      | Carlos Fierro (b) (4)          | 06 Apr 2021 02:47:03 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Karol Moore (b) (4) | 30 Mar 2021 13:49:13 |



US3312465

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 14 Apr 2021 08:06:54 |
| User entered 'VISIT4' | System           | 30 Mar 2021 13:49:13 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Were vital signs assessed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered 'No (N)'     | (b) (4)               | 30 Mar 2021 13:49:48 |
|                           | Karol Moore (b) (4)   |                      |
|                           | (b) (4)               |                      |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 30 Mar 2021 13:49:48 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Time of assessment (00:00-23:59)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 30 Mar 2021 13:49:48 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Vital Signs Date and Time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 08:06:54 |
| User entered empty. | System           | 30 Mar 2021 13:49:48 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Temperature (xxx.x)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)               | 30 Mar 2021 13:49:48 |
|                           | Karol Moore (b) (4)   |                      |
|                           | (b) (4)               |                      |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Route of measurement](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)               | 30 Mar 2021 13:49:48 |
|                           | Karol Moore (b) (4)   |                      |
|                           | (b) (4)               |                      |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[If Other, specify](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 30 Mar 2021 13:49:48 |



US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Pulse \(xxx\)](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4) | 30 Mar 2021 13:49:48 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 08:06:54 |
| User entered empty. | System           | 30 Mar 2021 13:49:48 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 30 Mar 2021 13:49:48 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Respiratory Rate units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 08:06:54 |
| User entered empty. | System           | 30 Mar 2021 13:49:48 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Systolic Blood Pressure (xxx)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)               | 30 Mar 2021 13:49:48 |
|                           | Karol Moore (b) (4)   |                      |
|                           | (b) (4)               |                      |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 08:06:54 |
| User entered empty. | System           | 30 Mar 2021 13:49:48 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure (xxx)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 30 Mar 2021 13:49:48 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 14 Apr 2021 08:06:54 |
| User entered empty. | System           | 30 Mar 2021 13:49:48 |



US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 08:06:54 |
|                   |                  |                      |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:03:25

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 08:06:54 |
|                   |                  |                      |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:25

[Was the physical examination performed?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 30 Mar 2021 13:49:54 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:25

Date of examination (dd MMM yyyy)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 14 Apr 2021 08:06:54 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered '26 Mar 2021' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 30 Mar 2021 13:49:54 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

[Was the sample collected?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 30 Mar 2021 13:50:15 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

Collection date (*dd MMM yyyy*)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 14 Apr 2021 08:06:54 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered '26 Mar 2021' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 30 Mar 2021 13:50:15 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

Collection time (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered '10:22'      | (b) (4)               | 30 Mar 2021 13:50:15 |
|                           | Karol Moore (b) (4)   |                      |
|                           | (b) (4)               |                      |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 14 Apr 2021 08:06:54 |
| User entered '26 Mar 2021 10:22' | System           | 30 Mar 2021 13:50:15 |



US3312465

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Is the participant continuing to the next visit?](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 14 Apr 2021 08:06:54 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>Karol Moore (b) (4) | 30 Mar 2021 13:50:30 |

US3312465

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:03:25

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 08:06:54 |
| User entered 'I'  | System           | 30 Mar 2021 13:50:30 |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Was this visit performed?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                           |                       |                      |
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 04 Feb 2021 19:19:28 |
|                           |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                            |                       |                      |
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                            | (b) (4)               |                      |
| User entered '02 Feb 2021' | (b) (4), (b) (6)      | 04 Feb 2021 19:19:28 |
|                            |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                                |                       |                      |
| User signature succeeded.      | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                                | (b) (4)               |                      |
| User entered 'Clinic (Clinic)' | (b) (4), (b) (6)      | 04 Feb 2021 19:19:28 |
|                                |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:03:25

[Folder OID](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 29 Apr 2021 13:12:22 |
|                              |                  |                      |
| User entered 'UNBLND_DECIDE' | System           | 04 Feb 2021 19:19:28 |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:25

Date of updated informed consent (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                            |                       |                      |
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                            | (b) (4)               |                      |
| User entered '02 Feb 2021' | (b) (4), (b) (6)      | 04 Feb 2021 19:19:47 |
|                            |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:25

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit                                      | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|  |                       |                      |
| User signature succeeded.                  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|  | (b) (4)               |                      |
| User entered '0' WR# 5295537               | System                | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System                | 06 Mar 2021 14:34:19 |



US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:25

[Was the participant unblinded?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                           |                       |                      |
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 04 Feb 2021 19:19:47 |
|                           |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:25

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|   |                       |                      |
| User signature succeeded.   | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|   | (b) (4)               |                      |
| User entered 'AMENDMENT 6 OR LATER<br>(AMENDMENT 6 OR LATER)' WR# 5295537 | System                | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint.                                | System                | 06 Mar 2021 14:34:19 |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:25

Date of unblinding (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                            |                       |                      |
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                            | (b) (4)               |                      |
| User entered '02 Feb 2021' | (b) (4), (b) (6)      | 04 Feb 2021 19:19:47 |
|                            |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:25

[Participant randomization assignment](#)

| Audit                                | User                  | Time (GMT)           |
|--------------------------------------|-----------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                                      |                       |                      |
| User signature succeeded.            | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                                      | (b) (4)               |                      |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4), (b) (6)      | 04 Feb 2021 19:19:47 |
|                                      |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:25

[Actual Dose 1](#)

| Audit                                | User                  | Time (GMT)           |
|--------------------------------------|-----------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                                      |                       |                      |
| User signature succeeded.            | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                                      | (b) (4)               |                      |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4), (b) (6)      | 04 Feb 2021 19:19:47 |
|                                      |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:25

[Actual Dose 2](#)

| Audit                                | User                  | Time (GMT)           |
|--------------------------------------|-----------------------|----------------------|
| Data hard locked.                    | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                                      |                       |                      |
| User signature succeeded.            | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                                      | (b) (4)               |                      |
| User entered 'mRNA-1273 (mRNA-1273)' | (b) (4), (b) (6)      | 04 Feb 2021 19:19:47 |
|                                      |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:25

[Will participant receive mRNA-1273?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                           |                       |                      |
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | (b) (4), (b) (6)      | 04 Feb 2021 19:19:47 |
|                           |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:25

[Placebo Only Flag](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 13:12:22 |
|                     |                  |                      |
| User entered empty. | System           | 04 Feb 2021 19:19:47 |



US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:03:25

[Continuing with mRNA-1273](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 29 Apr 2021 13:12:22 |
|                     |                  |                      |
| User entered empty. | System           | 04 Feb 2021 19:19:47 |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                           |                       |                      |
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 04 Feb 2021 19:19:54 |
|                           |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

Collection date (*dd MMM yyyy*)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                            |                       |                      |
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                            | (b) (4)               |                      |
| User entered '02 Feb 2021' | (b) (4), (b) (6)      | 04 Feb 2021 19:19:54 |
|                            |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

Collection time (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                           |                       |                      |
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered '12:27'      | (b) (4), (b) (6)      | 04 Feb 2021 19:19:54 |
|                           |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:03:25

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Apr 2021 13:12:22 |
|                                  |                  |                      |
| User entered '02 Feb 2021 12:27' | System           | 04 Feb 2021 19:19:54 |

US3312465

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:03:25**

[Was the sample collected?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                           |                       |                      |
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 04 Feb 2021 19:20:05 |
|                           |                       |                      |

US3312465

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:03:25**

[Collection date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                            |                       |                      |
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                            | (b) (4)               |                      |
| User entered '02 Feb 2021' | (b) (4), (b) (6)      | 04 Feb 2021 19:20:05 |
|                            |                       |                      |

US3312465

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:03:25

Collection time (00:00 - 23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)      | 29 Apr 2021 13:12:22 |
|                           |                       |                      |
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered '12:26'      | (b) (4), (b) (6)      | 04 Feb 2021 19:20:05 |
|                           |                       |                      |



US3312465

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:03:25**

[Collection Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 29 Apr 2021 13:12:22 |
|                                  |                  |                      |
| User entered '02 Feb 2021 12:26' | System           | 04 Feb 2021 19:20:05 |

US3312465

Folder: Unscheduled 02 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:03:25

[Visit Date](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 25 Apr 2021 21:24:25 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '02 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:20:43 |

US3312465

Folder: Unscheduled 02 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:03:25

[Physical Exam](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 25 Apr 2021 21:24:25 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:20:43 |

US3312465

Folder: Unscheduled 02 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:03:25

[Vital Signs](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 25 Apr 2021 21:24:25 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:20:43 |

US3312465

Folder: **Unscheduled 02 Feb 2021**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 17:03:25**

[Immunogenicity Assessment](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 25 Apr 2021 21:24:25 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:20:43 |

US3312465

Folder: Unscheduled 02 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 17:03:25

[Pregnancy Test](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 25 Apr 2021 21:24:25 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:20:43 |

US3312465

Folder: Unscheduled 02 Feb 2021

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:25

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 25 Apr 2021 21:24:37 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:20:51 |

US3312465

Folder: Unscheduled 02 Feb 2021

Form: Physical Examination

Generated On: 09 Jun 2021 17:03:25

Date of examination (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 25 Apr 2021 21:24:37 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '02 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:20:51 |



US3312465

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:03:25

[Did the participant experience any adverse events?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 May 2021 16:00:56 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 12 Mar 2021 16:03:01 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:30:17 |

US3312465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[AEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:24:19 |
| User entered<br>'USA-US300-2021-mRNA-1273-P301000021' | System                      | 29 Mar 2021 17:24:15 |
| User entered 'New'                                    | (b) (4), (b) (6)            | 29 Mar 2021 17:24:15 |

US3312465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[Adverse event](#)

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4)            | 08 Apr 2021 16:15:49 |
| User closed query 'For coding purposes, please clarify/provide more information fro term EXACERBATION and update the term with your response.' (Site from Coder).  | (b) (4)<br>(b) (4), (b) (6)      | 11 Mar 2021 23:05:05 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression aggravated - version MedDRA\\23.0.                                      | Coder Import (b) (4)<br>(b) (4)  | 08 Feb 2021 20:34:53 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)  | 08 Feb 2021 20:34:53 |
| Data point term sent to Coder  | System                           | 08 Feb 2021 20:34:16 |
| Query 'For coding purposes, please clarify/provide more information fro term EXACERBATION and update the term with your response.' answered with 'UPDATED' (Site from Coder).  | Monica Atwood (b) (4)<br>(b) (4) | 08 Feb 2021 20:34:13 |
| Coding entries removed.  | Monica Atwood (b) (4)<br>(b) (4) | 08 Feb 2021 20:34:01 |
| User entered 'EXACERBATION OF DEPRESSION' reason for change: Data Entry Error  | Monica Atwood (b) (4)<br>(b) (4) | 08 Feb 2021 20:34:01 |
| User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: General signs and symptoms NEC, PT: Ill-defined disorder, LLT: Ill-defined disorder - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4)  | 04 Feb 2021 21:04:28 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)  | 04 Feb 2021 21:04:28 |
| User opened query 'For coding purposes, please clarify/provide more information fro term EXACERBATION and update the term with your response.' (Site from Coder).  | (b) (4), (b) (6)                 | 04 Feb 2021 21:03:38 |
| Data point term sent to Coder  | System                           | 04 Feb 2021 19:35:27 |
| User entered 'exacerbation'  | (b) (4), (b) (6)                 | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[Was this a medically-attended AE?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 08 Apr 2021 16:15:49 |
|                           | (b) (4)               |                      |
| User entered 'Yes (Y)'    | (b) (4), (b) (6)      | 04 Feb 2021 19:34:38 |
|                           |                       |                      |

US3312465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |

US3312465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

Start date (dd MMM yyyy)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User signature succeeded.   | Carlos Fierro (b) (4) | 08 Apr 2021 16:15:49 |
|   | (b) (4)               |                      |
| User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | System                | 26 Mar 2021 16:32:36 |
| User entered '15 Dec 2020' reason for change: Data Entry Error                          | (b) (4), (b) (6)      | 26 Mar 2021 16:32:36 |
|   |                       |                      |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System                | 04 Feb 2021 19:34:38 |
| User entered 'un Dec 2020' (non-conformant).  | (b) (4), (b) (6)      | 04 Feb 2021 19:34:38 |
|   |                       |                      |

US3312465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

Start time (00:00-23:59)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[Ongoing?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).             | (b) (4), (b) (6)      | 09 Apr 2021 14:07:56 |
| User signature succeeded.   | Carlos Fierro (b) (4) | 08 Apr 2021 16:15:49 |
|   | (b) (4)               |                      |
| User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).   | System                | 08 Apr 2021 15:52:23 |
| User entered 'No (N)' reason for change: Data Entry Error   | (b) (4), (b) (6)      | 08 Apr 2021 15:52:23 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety). | (b) (4), (b) (6)      | 08 Apr 2021 15:52:09 |
| User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).   | System                | 08 Apr 2021 15:45:20 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).             | (b) (4), (b) (6)      | 05 Apr 2021 19:16:18 |
| User entered 'Yes (Y)'  | (b) (4), (b) (6)      | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

If not Ongoing, end date (*dd MMM yyyy*)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '31 Mar 2021' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:45:20 |
| User entered empty.  | (b) (4), (b) (6)            | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

End time (00:00-23:59)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 08 Apr 2021 16:15:49 |
|                           | (b) (4)               |                      |
| User entered empty.       | (b) (4), (b) (6)      | 04 Feb 2021 19:34:38 |
|                           |                       |                      |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[Severity](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User signature succeeded.                          | Carlos Fierro (b) (4) | 08 Apr 2021 16:15:49 |
| User entered 'Grade 3/Severe (Grade 3/Severe)'     | (b) (4)               | 26 Mar 2021 16:49:23 |
| reason for change: Data Entry Error                | (b) (4), (b) (6)      |                      |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4), (b) (6)      | 04 Feb 2021 19:34:38 |
|  |                       |                      |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[Is the adverse event serious?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User signature succeeded.   | Carlos Fierro (b) (4) | 08 Apr 2021 16:15:49 |
|   | (b) (4)               |                      |
| User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System). | System                | 26 Mar 2021 16:49:46 |
| User entered 'Yes (Y)' reason for change: Data Entry Error  | (b) (4), (b) (6)      | 26 Mar 2021 16:49:46 |
| User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System). | System                | 26 Mar 2021 16:49:23 |
| User entered 'No (N)'   | (b) (4), (b) (6)      | 04 Feb 2021 19:34:38 |
|   |                       |                      |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).<br>User signature succeeded. | (b) (4), (b) (6)      | 09 Apr 2021 14:08:19 |
|   | Carlos Fierro (b) (4) | 08 Apr 2021 16:15:49 |
| Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'emailed 08mar2021' (Site from Safety).        | (b) (4), (b) (6)      | 08 Apr 2021 16:05:30 |
| User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).                              | (b) (4), (b) (6)      | 05 Apr 2021 19:16:33 |
| User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).   | (b) (4), (b) (6)      | 29 Mar 2021 11:14:36 |
| Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'updated' (Site from System).   | (b) (4), (b) (6)      | 26 Mar 2021 16:50:52 |
| User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).   | System                | 26 Mar 2021 16:49:23 |
| User entered '1' reason for change: Data Entry Error  | (b) (4), (b) (6)      | 26 Mar 2021 16:49:23 |
| User entered '0'  | (b) (4), (b) (6)      | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '02 Mar 2021' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 16:49:23 |
| User entered empty.  | (b) (4), (b) (6)            | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (*dd MMM yyyy*)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '05 Mar 2021' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 16:49:23 |
| User entered empty.  | (b) (4), (b) (6)            | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |

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Form: Adverse Events (1)

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[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |



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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 08 Apr 2021 16:15:49 |
|                           | (b) (4)               |                      |
| User entered '0'          | (b) (4), (b) (6)      | 04 Feb 2021 19:34:38 |
|                           |                       |                      |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

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Action taken with investigational product

| Audit  | User                             | Time (GMT)           |
|--|----------------------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4)            | 08 Apr 2021 16:15:49 |
| User closed query 'Per CDM: Per CCGs, if adverse event started after last dose then Action Taken With Investigational Product should be "Not Applicable". Please confirm and reconcile.' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)      | 29 Mar 2021 11:14:38 |
| Query 'Per CDM: Per CCGs, if adverse event started after last dose then Action Taken With Investigational Product should be "Not Applicable". Please confirm and reconcile.' answered with 'updated' (Site from DM). | (b) (4), (b) (6)                 | 26 Mar 2021 16:32:51 |
| User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error   | (b) (4), (b) (6)                 | 26 Mar 2021 16:32:44 |
| User opened query 'Per CDM: Per CCGs, if adverse event started after last dose then Action Taken With Investigational Product should be "Not Applicable". Please confirm and reconcile.' (Site from DM).             | (b) (4), (b) (6)                 | 10 Feb 2021 19:49:36 |
| User entered 'None (NONE)' reason for change: Data Entry Error   | Monica Atwood (b) (4)<br>(b) (4) | 08 Feb 2021 20:34:54 |
| User entered 'Not Applicable (NOT APPLICABLE)'   | (b) (4), (b) (6)                 | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[None](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[Concomitant Medication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '1'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User closed query 'PV Query: As per the narrative, the event has been resolved. Kindy update the event outcome on the CRF.' (Site from Safety).             | (b) (4), (b) (6)      | 09 Apr 2021 14:08:39 |
| User signature succeeded.   | Carlos Fierro (b) (4) | 08 Apr 2021 16:15:49 |
| Query 'PV Query: As per the narrative, the event has been resolved. Kindy update the event outcome on the CRF.' answered with 'updated' (Site from Safety). | (b) (4), (b) (6)      | 08 Apr 2021 15:53:30 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error  | (b) (4), (b) (6)      | 08 Apr 2021 15:45:20 |
| User opened query 'PV Query: As per the narrative, the event has been resolved. Kindy update the event outcome on the CRF.' (Site from Safety).             | (b) (4), (b) (6)      | 05 Apr 2021 19:16:04 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'  | (b) (4), (b) (6)      | 04 Feb 2021 19:34:38 |



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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:34:38 |

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User closed query 'PV Query: Please provide date of negative COVID test. If unknown, please indicate so. ' (Site from Safety).   | (b) (4), (b) (6)               | 16 Apr 2021 13:49:47 |
| User closed query 'PV Query: Please confirm if benzodiazepine abuse, cannabis use disorder, and alcohol disorder should be reported as AE/SAE. ' (Site from Safety).   | (b) (4), (b) (6)               | 16 Apr 2021 13:49:45 |
| Query 'PV Query: Please provide date of negative COVID test. If unknown, please indicate so. ' answered with 'NEGATIVE COVID-19 TEST OCCURRED ON DAY OF CHECK-IN 02MAR2021' (Site from Safety).  | Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:20:35 |
| Query 'PV Query: Please confirm if benzodiazepine abuse, cannabis use disorder, and alcohol disorder should be reported as AE/SAE. ' answered with 'ADDED TO MED HISTORY' (Site from Safety).  | Karol Moore (b) (4)<br>(b) (4) | 15 Apr 2021 19:10:16 |
| User opened query 'PV Query: Please provide date of negative COVID test. If unknown, please indicate so. ' (Site from Safety).   | (b) (4), (b) (6)               | 14 Apr 2021 12:02:26 |
| User opened query 'PV Query: Please confirm if benzodiazepine abuse, cannabis use disorder, and alcohol disorder should be reported as AE/SAE. ' (Site from Safety).   | (b) (4), (b) (6)               | 14 Apr 2021 12:00:03 |
| User closed query 'Per DM CLR: Narrative = INCREASED DOSE OF TRAZADONE. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).  | (b) (4), (b) (6)               | 09 Apr 2021 15:13:32 |
| User closed query 'Per DM CLR: Narrative = SUBJECT ADMITS TO FOUR SIMILAR SUCH ATTEMPTS SINCE 2016 (SUICIDE ATTEMPT). However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM). | (b) (4), (b) (6)               | 09 Apr 2021 15:13:11 |
| User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).  | (b) (4), (b) (6)               | 09 Apr 2021 14:08:55 |
| User closed query 'PV Query: Kindly report suicide attempt as separate SAE.' (Site from Safety).   | (b) (4), (b) (6)               | 09 Apr 2021 14:08:47 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| Query 'Per DM CLR: Narrative = INCREASED DOSE OF TRAZADONE. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).  | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:05:13 |
| Query 'Per DM CLR: Narrative = SUBJECT ADMITS TO FOUR SIMILAR SUCH ATTEMPTS SINCE 2016 (SUICIDE ATTEMPT). However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'updated med history' (Site from DM). | (b) (4), (b) (6)            | 08 Apr 2021 16:05:08 |
| Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'done-negative per subject' (Site from Safety).  | (b) (4), (b) (6)            | 08 Apr 2021 16:00:48 |
| Query 'PV Query: Kindly report suicide attempt as separate SAE.' answered with 'updated' (Site from Safety).   | (b) (4), (b) (6)            | 08 Apr 2021 15:53:34 |
| User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).  | (b) (4), (b) (6)            | 05 Apr 2021 19:15:53 |
| User opened query 'PV Query: Kindly report suicide attempt as separate SAE.' (Site from Safety).   | (b) (4), (b) (6)            | 05 Apr 2021 19:15:44 |
| User opened query 'Per DM CLR: Narrative = INCREASED DOSE OF TRAZADONE. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).  | (b) (4), (b) (6)            | 05 Apr 2021 03:02:13 |
| User opened query 'Per DM CLR: Narrative = SUBJECT ADMITS TO FOUR SIMILAR SUCH ATTEMPTS SINCE 2016 (SUICIDE ATTEMPT). However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).                         | (b) (4), (b) (6)            | 05 Apr 2021 03:02:00 |

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US3312465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[Narrative](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User entered 'SUBJ WAS SEEN 26MAR21 FOR D206 FOLLOW-UP, AT WHICH TIME HE REPORTED HOSP 02MAR21-05MAR21 After SUICIDE ATTEMPT. ON 02MAR21, SUBJ FOUND BY PARENT AFTER INGESTING UNK AMT OF ALPRAZOLAM&VODKA.TAKEN TO HOSP VIA EMS. SUBJ ADM TO 4 SIMILAR ATTEMPTS SINCE 2016, ALTHOUGH NOT PREV REPORTED TO SITE.AT TIME OF INITIAL SCREEN, SUBJ WAS NOTED TO HAVE HX OF DEPRESSION SINCE 2016, Tx WITH KLONIPIN SINCE APR2020. SEP2020, SUBJ REPORTED HE HAD BEEN PRESCRIBED ALPRAZOLAM IN APR2020 IN ADDITION TO KLONIPIN.DIDn'T FILL ALPRAZOLAM RX IN ATTEMPT TO CNTRL SX WITH MIN MEDs.ROUTINE TELEMED WITH PSYCHIATRIST RESULTED IN RENEWED ALPRAZOLAM RX D/t STABLE, BUT UNIMPROVED DEPRESSION.FEB2021, SUBJ BEGAN FLUOXITINE&TRAZADONE FOR EXAC OF DEPRESSION. After 02MAR21 SUICIDE ATTEMPT, SUBJ RX GABAPENTIN,INCR DOSE OF TRAZADONE&INSTR TO Dc KLONOPIN&ALPRAZOLAM.MEDS CURR MANAGED BY PCP, LAST SEEN 24MAR21. CURR ADMITS TO FEELING DEPRESSED BUT "BETTER SINCE GETTING OUT OF HOSP." DENIES SI. REPORTS LIVING WITH PARENTS&RETURNING TO WORK AND DAILY ACTIVITIES&NmL ROUTINE. PE UNREMARKABLE.Med rec reviewed confirming hosp 02Mar21-05Mar21 for alprazolam overdose.Presented to hosp with hx of taking 56mg of Alprazolam&2 shots ETOH over 13 hrs & reg sched klonazepam. (b) (6) parents called EMS. Subj somewhat drowsy in ER, very little other severe symptoms. Subj denied suicide attempt, stated overdose d/t cycling thru forgetting he took alprazolam&retaking it, until he realized he had taken | Heather Barker (b) (4)<br>(b) (4) | 31 Mar 2021 22:00:31 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[Narrative](#)

| Audit  | User | Time (GMT) |
|--|------|------------|
| 56mg. Has hx of depression&anxiety.Cited financial&job stress&panic attacks,low energy,low concentration&low self-worth as contributing factors.UDS pos for benzos&marijuana. He endorsed freq ETOH use. Blood ETOH reported as "11." His mom concerned subj was diverting meds. Benzos dc'd during hosp,staff surprised at lack of withdrawal sympt. Subj curr managed by PCP&outpt psych.Denies SI, back to nml pre-event routine, incl work.Exac of pre-existing depression resolved.Subj back to baseline.Will close SAE. Not related to IP.' reason for change: New Information |      |            |

US3312465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:03:25

[Narrative](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User entered 'Subject was seen on 26Mar2021 for D206 follow-up, at which time he reported hospitalization from 02Mar2021 to 05Mar2021 following suicide attempt. On 02Mar2021, subject was found by parent after ingesting unknown amount of Alprazolam and vodka, and taken to local hospital via EMS. Subject admits to four similar such attempts since 2016, although not previously reported to our site. At time of initial screening, subject was noted to have hx of depression since 2016, treated with Klonopin since Apr2020. In Sep2020, subject reported that he had been prescribed Alprazolam in Apr2020 in addition to Klonopin, but did not fill Alprazolam rx in attempt to control sx with minimal medication. Per patient, routine telemedicine visit with psychiatrist resulted in renewed Alprazolam rx due to stable, but unimproved depression. In Feb2021, subject began taking Fluoxetine and Trazadone for exacerbation of depression. Following 02Mar2021 suicide attempt, subject was prescribed Gabapentin and increased dose of Trazadone and instructed to discontinue Klonopin and Alprazolam. Medications currently managed by PCP, last seen on 24Mar2021. Subject awaiting first appointment with new psychiatrist referred by PCP. Currently admits to feeling depressed but "better since getting out of the hospital." Denies suicidal ideation. Reports living with his parents and returning to work and daily activities as per normal routine. Physical exam unremarkable. Awaiting records' reason for change: Data Entry Error | (b) (4), (b) (6) | 26 Mar 2021 16:49:23 |
| User entered empty.   | (b) (4), (b) (6) | 04 Feb 2021 19:34:38 |

**US3312465**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 26 Mar 2021 16:49:46 |
| User entered '0' | System | 04 Feb 2021 19:34:38 |

**US3312465**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 04 Feb 2021 19:34:38 |



US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[AEID](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User signature succeeded.   | Carlos Fierro (b) (4) | 09 Apr 2021 15:59:36 |
|   | (b) (4)               |                      |
| User entered<br>'USA-US300-2021-mRNA-1273-P301000021'             | (b) (4), (b) (6)      | 09 Apr 2021 14:09:49 |
| DataPoint activated with code reason code Data<br>required.       | (b) (4), (b) (6)      | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not<br>required. | (b) (4), (b) (6)      | 26 Mar 2021 16:51:24 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Adverse event](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4)           | 08 Apr 2021 16:15:49 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicide attempt, LLT: Suicide attempt - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 08 Apr 2021 15:38:54 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)            | 08 Apr 2021 15:38:54 |
| Data point term sent to Coder  | System                          | 08 Apr 2021 15:38:24 |
| DataPoint activated with code reason code Data required.   | (b) (4), (b) (6)                | 08 Apr 2021 15:38:20 |
| Data point term sent to Coder  | System                          | 26 Mar 2021 16:52:08 |
| DataPoint inactivated with code reason code Data not required.   | (b) (4), (b) (6)                | 26 Mar 2021 16:51:24 |
| User coded data point as SOC: Psychiatric disorders, HLGT: Suicidal and self-injurious behaviours NEC, HLT: Suicidal and self-injurious behaviour, PT: Suicide attempt, LLT: Suicide attempt - version MedDRA\\23.0. | Coder Import (b) (4)            | 26 Mar 2021 16:40:33 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)            | 26 Mar 2021 16:40:33 |
| Data point term sent to Coder  | System                          | 26 Mar 2021 16:39:54 |
| User entered 'Suicide attempt'   | (b) (4), (b) (6)                | 26 Mar 2021 16:39:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Was this a medically-attended AE?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered 'Yes (Y)'   | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Was this a Solicited Adverse Reaction?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered 'No (N)'  | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered 'No (N)'  | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

Start date (dd MMM yyyy)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered '02 Mar 2021'                                     | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

Start time (00:00-23:59)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered empty.  | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[AE start date and time \(derived\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 26 Mar 2021 16:51:24 |
| User entered empty.  | System           | 26 Mar 2021 16:39:52 |



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Ongoing?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered 'No (N)'  | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

If not Ongoing, end date (dd MMM yyyy)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered '02 Mar 2021'                                     | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

End time (00:00-23:59)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered empty.  | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[AE End Date and Time \(derived\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 26 Mar 2021 16:51:24 |
| User entered empty.  | System           | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Severity](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered 'Grade 3/Severe (Grade 3/Severe)'                 | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Is the adverse event serious?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered 'Yes (Y)'   | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Death](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered '0'   | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Life threatening](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered '0'   | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered '1'   | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

Hospital Admission Date (*dd MMM yyyy*)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered '02 Mar 2021'                                     | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

Hospital Discharge Date (dd MMM yyyy)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered '05 Mar 2021'                                     | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Admitted to ICU?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered 'No (N)'  | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Number of Days in ICU](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered empty.  | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Persistent or significant disability or incapacity](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered '0'   | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Congenital anomaly or birth defect](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered '0'   | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Other medically important event](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered '0'   | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Relationship to investigational product](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered 'Not Related (NOT RELATED)'                       | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Relationship to Study Procedure](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered 'Not Related (NOT RELATED)'                       | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Action taken with investigational product](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered 'Not Applicable (NOT APPLICABLE)'                 | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

None

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered '0'   | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Concomitant Medication](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered '1'   | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Concomitant Procedure](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered '0'   | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Outcome](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'         | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered empty.  | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |



US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Narrative](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| DataPoint activated with code reason code Data required.  | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required.  | (b) (4), (b) (6)            | 26 Mar 2021 16:51:24 |
| User entered 'Subject was seen on 26Mar2021 for D206 follow-up, at which time he reported hospitalization from 02Mar2021 to 05Mar2021 following suicide attempt. On 02Mar2021, subject was found by parent after ingesting unknown amount of Alprazolam and vodka, and taken to local hospital via EMS. Subject admits to four similar such attempts since 2016, although not previously reported to our site. At time of initial screening, subject was noted to have hx of depression since 2016, treated with Klonopin since Apr2020. In Sep2020, subject reported that he had been prescribed Alprazolam in Apr2020 in addition to Klonopin, but did not fill Alprazolam rx in attempt to control sx with minimal medication. Per patient, routine telemedicine visit with psychiatrist resulted in renewed Alprazolam rx due to stable, but unimproved depression. In Feb2021, subject began taking Fluoxetine and Trazadone for exacerbation of depression. Following 02Mar2021 suicide attempt, subject was prescribed Gabapentin and increased dose of Trazadone and instructed to discontinue Klonopin and Alprazolam. Medications currently managed by PCP, last seen on 24Mar2021. Subject awaiting first appointment with new psychiatrist referred by PCP. Currently admits to feeling depressed but "better since getting out of the hospital." Denies suicidal ideation. Reports living with his parents and returning to work and daily activities as per normal routine. Physical exam unremarkable. Awaiting records' | (b) (4), (b) (6)            | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

Serious Adverse Event Derived (CSA Programming Field Only)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 26 Mar 2021 16:51:24 |
| User entered 'I'   | System           | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 26 Mar 2021 16:51:24 |
| User entered 'I'   | System           | 26 Mar 2021 16:39:52 |

US3312465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:03:25

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 08 Apr 2021 15:38:20 |
| DataPoint inactivated with code reason code Data not required. | (b) (4), (b) (6) | 26 Mar 2021 16:51:24 |
| User entered '0'   | System           | 26 Mar 2021 16:39:52 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:03:25

Were any prior/concomitant medications and/or vaccinations taken?

| Audit   | User                           | Time (GMT)           |
|---|--------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)               | 03 May 2021 16:00:56 |
| User signature succeeded.   | Carlos Fierro (b) (4)          | 09 Apr 2021 15:59:36 |
| 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.<br>' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)    | 09 Apr 2021 15:53:56 |
| 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.<br>' answered with 'NA. SUBJECT ANSWERED "YES" IN ERROR. CONFIRMED WITH SUBJECT HE HAS NOT HAD ANY FACIAL COSMETIC INJECTIONS' (Site from DM). | Karol Moore (b) (4)<br>(b) (4) | 09 Apr 2021 00:09:38 |
| 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.<br>' (Site from DM).   | (b) (4), (b) (6)               | 23 Mar 2021 10:31:25 |
| Query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.<br>' canceled (Site from DM).   | (b) (4), (b) (6)               | 23 Mar 2021 10:31:22 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 17:03:25**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| User opened query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.<br />' (Site from DM). | (b) (4), (b) (6)               | 19 Mar 2021 05:48:40 |
| User entered 'Yes (Y)'   | Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:20:00 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:25

[Name of Medication](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 01 May 2021 10:01:17 |
| User signature succeeded.   | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM, PRODUCTSYNONYM: KLONOPIN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 22 Sep 2020 23:21:49 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)  | 22 Sep 2020 23:21:49 |
| Data point term sent to Coder   | System                | 22 Sep 2020 23:20:44 |
| User entered 'klonopin'   | Karol Moore (b) (4)   | 22 Sep 2020 23:20:26 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:25

[Prophylaxis](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:17 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:20:26 |



US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:25

[Indication](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:17 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'anxiety'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:20:26 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose per administration](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:17 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'I'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:20:26 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:25

[Dose unit](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:17 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'mg (mg)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:20:26 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:03:25**

If dose unit is Other, specify

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:17 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:20:26 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:25

[Frequency](#)

| Audit                          | User                                      | Time (GMT)           |
|--------------------------------|---|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                          | 01 May 2021 10:01:17 |
| User signature succeeded.      | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'once daily (QD)' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:20:26 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:25

If frequency is Other, specify

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:17 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:20:26 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Route of administration](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 01 May 2021 10:01:17 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'Oral (ORAL)' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:20:26 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:03:25**

If route of administration is Other, specify

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:17 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:20:26 |



US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                                      | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                          | 01 May 2021 10:01:17 |
| User signature succeeded.  | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'un Apr 2020' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:20:26 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:17 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:20:26 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:25

[Ongoing?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 01 May 2021 10:01:17 |
| User signature succeeded.                                 | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)               | 29 Mar 2021 22:59:16 |
| User entered 'Yes (Y)'                                    | Karol Moore (b) (4)   | 22 Sep 2020 23:20:26 |
|   | (b) (4)               |                      |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:03:25

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 01 May 2021 10:01:17 |
| User signature succeeded.                                      | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered '02 Mar 2021' reason for change: Data Entry Error | (b) (4)               | 29 Mar 2021 22:59:16 |
| User entered empty.  | Karol Moore (b) (4)   | 22 Sep 2020 23:20:26 |
|  | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:17 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 22 Sep 2020 23:20:26 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 10:01:17 |
| User entered '1'  | System           | 22 Sep 2020 23:20:26 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 10:01:17 |
| User entered '1'  | System           | 22 Sep 2020 23:20:26 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 01 May 2021 10:01:17 |
| User entered '804 (804)' | System           | 22 Sep 2020 23:20:26 |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:03:25

[Name of Medication](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4)                      | 06 Apr 2021 02:47:03 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 22 Sep 2020 23:22:51 |
| 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)            | 22 Sep 2020 23:22:51 |
| Data point term sent to Coder  | System                                     | 22 Sep 2020 23:21:45 |
| User entered 'albuterol'   | Karol Moore (b) (4)<br>(b) (4)             | 22 Sep 2020 23:20:55 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Indication](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'asthma'     | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|                           | (b) (4)               |                      |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered '180'        | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|                           | (b) (4)               |                      |

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose unit](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'ug (ug)'    | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered empty.       | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Frequency](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded.      | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                                | (b) (4)               |                      |
| User entered 'as needed (PRN)' | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|                                | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered empty.       | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|                           | (b) (4)               |                      |



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Route of administration](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User signature succeeded.   | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|   | (b) (4)               |                      |
| User entered 'Respiratory (Inhalation)<br>(RESPIRATORY (INHALATION))' | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|   | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered empty.       | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                            | (b) (4)               |                      |
| User entered 'un UNK 2018' | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|                            | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered '0'          | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'Yes (Y)'    | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered empty.       | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Karol Moore (b) (4)   | 22 Sep 2020 23:20:55 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Sep 2020 23:20:55 |



US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Sep 2020 23:20:55 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 22 Sep 2020 23:20:55 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:25

Name of Medication

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 01 May 2021 10:01:21 |
| User signature succeeded.   | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 24 Nov 2020 20:50:31 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)  | 24 Nov 2020 20:50:31 |
| Data point term sent to Coder   | System                | 24 Nov 2020 20:49:15 |
| Coding entries removed.   | Karol Moore (b) (4)   | 24 Nov 2020 20:49:08 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 18 Oct 2020 02:20:30 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)  | 18 Oct 2020 02:20:30 |
| Data point term sent to Coder   | System                | 17 Oct 2020 21:34:20 |
| User entered 'ALPRAZOLAM'   | Karol Moore (b) (4)   | 17 Oct 2020 21:33:51 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:25

[Prophylaxis](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:21 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:33:51 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:25

[Indication](#)

| Audit  | User                           | Time (GMT)           |
|--|--------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)               | 01 May 2021 10:01:21 |
| User signature succeeded.  | Carlos Fierro (b) (4)          | 06 Apr 2021 02:47:03 |
| User closed query 'Per DM CLR: This Con Med was added on 30 SEP 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)    | 27 Nov 2020 05:44:22 |
| Query 'Per DM CLR: This Con Med was added on 30 SEP 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 'NOT AN AE. CORRECT AS ENTERED. NOT A WORSENING OR EXACERBATION. SUBJECT REPORTS ANXIETY HAS BEEN UNCHANGED AND POORLY MANAGED, RE-PRESCRIBED ALPRAZOLAM' (Site from DM). | Karol Moore (b) (4)<br>(b) (4) | 24 Nov 2020 20:50:50 |
| User entered 'ANXIETY' reason for change: Data Entry Error   | Karol Moore (b) (4)<br>(b) (4) | 24 Nov 2020 20:49:08 |
| User opened query 'Per DM CLR: This Con Med was added on 30 SEP 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)               | 24 Nov 2020 08:41:18 |
| User entered 'ANOXETY'   | Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:33:51 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose per administration](#)

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 01 May 2021 10:01:21 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 06 Apr 2021 02:47:03 |
| User entered '0.5'        | (b) (4)<br>Karol Moore (b) (4) | 17 Oct 2020 21:33:51 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:25

[Dose unit](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:21 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'mg (mg)'    | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:33:51 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:03:25**

If dose unit is Other, specify

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:21 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:33:51 |



US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:25

[Frequency](#)

| Audit                          | User                                      | Time (GMT)           |
|--------------------------------|---|----------------------|
| Data hard locked.              | (b) (4), (b) (6)                          | 01 May 2021 10:01:21 |
| User signature succeeded.      | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'as needed (PRN)' | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:33:51 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:03:25**

[If frequency is Other, specify](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:21 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:33:51 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:03:25**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)      | 01 May 2021 10:01:21 |
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered 'Oral (ORAL)' | Karol Moore (b) (4)   | 17 Oct 2020 21:33:51 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:03:25**

If route of administration is Other, specify

| Audit                     | User                           | Time (GMT)           |
|---------------------------|--------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)               | 01 May 2021 10:01:21 |
| User signature succeeded. | Carlos Fierro (b) (4)          | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>Karol Moore (b) (4) | 17 Oct 2020 21:33:51 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:25

Start date (dd MMM yyyy)

| Audit                      | User                           | Time (GMT)           |
|----------------------------|--------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)               | 01 May 2021 10:01:21 |
| User signature succeeded.  | Carlos Fierro (b) (4)          | 06 Apr 2021 02:47:03 |
| User entered '30 Sep 2020' | (b) (4)<br>Karol Moore (b) (4) | 17 Oct 2020 21:33:51 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date completely unknown](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:21 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered '0'          | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:33:51 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:25

[Ongoing?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 01 May 2021 10:01:21 |
| User signature succeeded.                                 | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)               | 29 Mar 2021 22:59:29 |
| User entered 'Yes (Y)'                                    | Karol Moore (b) (4)   | 17 Oct 2020 21:33:51 |
|   | (b) (4)               |                      |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:03:25

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 01 May 2021 10:01:21 |
| User signature succeeded.                                      | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered '02 Mar 2021' reason for change: Data Entry Error | (b) (4)               | 29 Mar 2021 22:59:29 |
| User entered empty.  | Karol Moore (b) (4)   | 17 Oct 2020 21:33:51 |
|  | (b) (4)               |                      |



US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:03:25**

[Was this medication taken for solicited event?](#)

| Audit                     | User                                      | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                          | 01 May 2021 10:01:21 |
| User signature succeeded. | Carlos Fierro (b) (4)                     | 06 Apr 2021 02:47:03 |
| User entered 'No (N)'     | (b) (4)<br>Karol Moore (b) (4)<br>(b) (4) | 17 Oct 2020 21:33:51 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:03:25**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 10:01:21 |
| User entered empty. | System           | 17 Oct 2020 21:33:51 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 10:01:21 |
| User entered empty. | System           | 17 Oct 2020 21:33:51 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 10:01:21 |
| User entered empty. | System           | 17 Oct 2020 21:33:51 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:25

[Name of Medication](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 01 May 2021 10:01:24 |
| User signature succeeded.   | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 04 Feb 2021 22:40:29 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)  | 04 Feb 2021 22:40:29 |
| Data point term sent to Coder   | System                | 04 Feb 2021 19:29:17 |
| User entered 'fluoxetine'   | (b) (4), (b) (6)      | 04 Feb 2021 19:28:19 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:25

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:24 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:28:19 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:03:25**

[Indication](#)

| Audit                                     | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6)            | 01 May 2021 10:01:24 |
| User signature succeeded.                 | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'exacerbation of depression' | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:28:19 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:24 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '10'         | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:28:19 |



US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:25

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:24 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:28:19 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:03:25**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:24 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:28:19 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:25

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 01 May 2021 10:01:24 |
| User signature succeeded.      | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:28:19 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:03:25**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:24 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:28:19 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:03:25**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 10:01:24 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:28:19 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:03:25**

[If route of administration is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:24 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:28:19 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:25

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 10:01:24 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '02 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:28:19 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:24 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:28:19 |



US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:25

[Ongoing?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 10:01:24 |
| User signature succeeded.                                | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'No (N)' reason for change: New Information | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:51:59 |
| User entered 'Yes (Y)'                                   | (b) (4), (b) (6)            | 04 Feb 2021 19:28:19 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:25

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 10:01:24 |
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '05 Feb 2021' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:51:59 |
| User entered empty.  | (b) (4), (b) (6)            | 04 Feb 2021 19:28:19 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:03:25

[Was this medication taken for solicited event?](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 01 May 2021 10:01:24 |
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 04 Feb 2021 19:28:28 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 04 Feb 2021 19:28:28 |
| User entered 'No (N)' reason for change: Data Entry Error                              | (b) (4), (b) (6)      | 04 Feb 2021 19:28:28 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 04 Feb 2021 19:28:19 |
| User entered empty.  | (b) (4), (b) (6)      | 04 Feb 2021 19:28:19 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:03:25**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 10:01:24 |
| User entered '1'  | System           | 04 Feb 2021 19:28:19 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 10:01:24 |
| User entered '1'  | System           | 04 Feb 2021 19:28:19 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 01 May 2021 10:01:24 |
| User entered '804 (804)' | System           | 04 Feb 2021 19:28:19 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:25

Name of Medication

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                           | 01 May 2021 10:01:27 |
| User signature succeeded.  | Carlos Fierro (b) (4)                      | 06 Apr 2021 02:47:03 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: PSYCHOANALEPTICS, ATC:<br>ANTIDEPRESSANTS, ATC: OTHER<br>ANTIDEPRESSANTS, PRODUCT: TRAZODONE<br>- version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 06 Feb 2021 15:15:42 |
| 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)            | 06 Feb 2021 15:15:42 |
| Data point term sent to Coder  | System                                     | 04 Feb 2021 19:30:18 |
| User entered 'trazadone'   | (b) (4), (b) (6)                           | 04 Feb 2021 19:29:57 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:25

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:29:57 |



US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:25

[Indication](#)

| Audit                                     | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded.                 | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'exacerbation of depression' | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:29:57 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:25

[Dose per administration](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded.   | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| Signature has been broken.  | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:01:20 |
| User entered '10' reason for change: Data Entry Error   | (b) (4), (b) (6)            | 08 Apr 2021 16:01:20 |
| User signature succeeded.   | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.<br>' (Site from DM).              | (b) (4)<br>(b) (4), (b) (6) | 16 Mar 2021 16:07:11 |
| Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.<br>' answered with 'UPDATED.' (Site from DM). | (b) (4), (b) (6)            | 15 Mar 2021 14:47:24 |
| User entered '50' reason for change: Data Entry Error   | (b) (4), (b) (6)            | 15 Mar 2021 14:47:18 |
| User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.<br>' (Site from DM).              | (b) (4), (b) (6)            | 23 Feb 2021 08:13:35 |
| User entered '10'   | (b) (4), (b) (6)            | 04 Feb 2021 19:29:57 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:25

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:29:57 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:03:25**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:29:57 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:25

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded.      | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:29:57 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:03:25**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:29:57 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:25

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:29:57 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:03:25**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:29:57 |



US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:25

Start date (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '02 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:29:57 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:29:57 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:25

[Ongoing?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded.                                 | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:47:18 |
| User entered 'Yes (Y)'                                    | (b) (4), (b) (6)            | 04 Feb 2021 19:29:57 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:03:25

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded.                                      | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '01 Mar 2021' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:47:18 |
| User entered empty.  | (b) (4), (b) (6)            | 04 Feb 2021 19:29:57 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:03:25**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:27 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 04 Feb 2021 19:29:57 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:03:25**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 10:01:27 |
| User entered '1'  | System           | 04 Feb 2021 19:29:57 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 10:01:27 |
| User entered '1'  | System           | 04 Feb 2021 19:29:57 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 01 May 2021 10:01:27 |
| User entered '804 (804)' | System           | 04 Feb 2021 19:29:57 |



US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:25

[Name of Medication](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                           | 01 May 2021 10:01:31 |
| User signature succeeded.  | Carlos Fierro (b) (4)                      | 06 Apr 2021 02:47:03 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: PSYCHOANALEPTICS, ATC:<br>ANTIDEPRESSANTS, ATC: SELECTIVE<br>SEROTONIN REUPTAKE INHIBITORS,<br>PRODUCT: FLUOXETINE - version<br>WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 01 Mar 2021 14:54:54 |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)            | 01 Mar 2021 14:54:54 |
| Data point term sent to Coder  | System                                     | 01 Mar 2021 14:54:21 |
| User entered 'fluoxetine'  | (b) (4), (b) (6)                           | 01 Mar 2021 14:53:36 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:25

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:31 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:53:36 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:25

[Indication](#)

| Audit                                     | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6)            | 01 May 2021 10:01:31 |
| User signature succeeded.                 | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'exacerbation of depression' | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:53:36 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:31 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '20'         | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:53:36 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:31 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:53:36 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:03:25**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:31 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:53:36 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:25

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 01 May 2021 10:01:31 |
| User signature succeeded.      | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'once daily (QD)' | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:53:36 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:03:25**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:31 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:53:36 |



US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:25

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 10:01:31 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:53:36 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:03:25**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:31 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:53:36 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 10:01:31 |
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '06 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:53:36 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 10:01:31 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 01 Mar 2021 14:53:36 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:25

[Ongoing?](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)      | 01 May 2021 10:01:31 |
| User signature succeeded.                                 | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)               | 29 Mar 2021 23:00:12 |
| User entered 'Yes (Y)'                                    | Karol Moore (b) (4)   | 01 Mar 2021 14:53:36 |
|   | (b) (4)               |                      |
|   | (b) (4), (b) (6)      |                      |
|   |                       |                      |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:25

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 01 May 2021 10:01:31 |
| User signature succeeded.                                      | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered '05 Mar 2021' reason for change: Data Entry Error | (b) (4)               | 29 Mar 2021 23:00:12 |
| User entered empty.  | Karol Moore (b) (4)   | 01 Mar 2021 14:53:36 |
|  | (b) (4)               |                      |
|  | (b) (4), (b) (6)      |                      |
|  |                       |                      |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:03:25

[Was this medication taken for solicited event?](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)      | 01 May 2021 10:01:31 |
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)               | 01 Mar 2021 14:53:41 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 01 Mar 2021 14:53:41 |
| User entered 'No (N)' reason for change: Data Entry Error                              | (b) (4), (b) (6)      | 01 Mar 2021 14:53:41 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 01 Mar 2021 14:53:36 |
| User entered empty.  | (b) (4), (b) (6)      | 01 Mar 2021 14:53:36 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:03:25**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 10:01:31 |
| User entered '1'  | System           | 01 Mar 2021 14:53:36 |



US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 10:01:31 |
| User entered '1'  | System           | 01 Mar 2021 14:53:36 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 01 May 2021 10:01:31 |
| User entered '804 (804)' | System           | 01 Mar 2021 14:53:36 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:25

[Name of Medication](#)

| Audit   | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User signature succeeded.   | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|   | (b) (4)               |                      |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 15 Mar 2021 16:06:58 |
|   | (b) (4)               |                      |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)  | 15 Mar 2021 16:06:58 |
|   | (b) (4)               |                      |
| Data point term sent to Coder   | System                | 15 Mar 2021 14:49:51 |
| User entered 'HYDROXYZINE'  | (b) (4), (b) (6)      | 15 Mar 2021 14:49:03 |
|   |                       |                      |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:03:25

[Prophylaxis](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|  | (b) (4)               |                      |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                | 15 Mar 2021 14:49:51 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                | 15 Mar 2021 14:49:51 |
| User entered 'No (N)' reason for change: Data Entry Error                              | (b) (4), (b) (6)      | 15 Mar 2021 14:49:51 |
|  |                       |                      |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                | 15 Mar 2021 14:49:03 |
| User entered empty.  | (b) (4), (b) (6)      | 15 Mar 2021 14:49:03 |
|  |                       |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

[Indication](#)

| Audit                                     | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                 | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'EXACERBATION OF DEPRESSION' | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:03 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '100'        | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:03 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:03 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:03 |



US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

[Frequency](#)

| Audit                            | User                        | Time (GMT)           |
|----------------------------------|-----------------------------|----------------------|
| User signature succeeded.        | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'twice daily (BID)' | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:03 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:03 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:03 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:03 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '02 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:03 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:03 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:03 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:03 |



US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 15 Mar 2021 14:49:03 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '2' | System | 15 Mar 2021 14:49:03 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 15 Mar 2021 14:49:03 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 15 Mar 2021 14:49:03 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:03:25

[Name of Medication](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| User signature succeeded.   | Carlos Fierro (b) (4)                      | 06 Apr 2021 02:47:03 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 30 Mar 2021 14:18:07 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)            | 30 Mar 2021 14:18:07 |
| Data point term sent to Coder   | System                                     | 29 Mar 2021 23:01:24 |
| User entered 'GABAPENTIN'   | Karol Moore (b) (4)<br>(b) (4)             | 29 Mar 2021 23:00:59 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[Indication](#)

| Audit                                     | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User signature succeeded.                 | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|   | (b) (4)               |                      |
| User entered 'EXACERBATION OF DEPRESSION' | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|   | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered '100'        | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|                           | (b) (4)               |                      |



US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose unit](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'mg (mg)'    | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered empty.       | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[Frequency](#)

| Audit                                  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User signature succeeded.              | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|  | (b) (4)               |                      |
| User entered 'three times daily (TID)' | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|  | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered empty.       | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                            | (b) (4)               |                      |
| User entered 'Oral (ORAL)' | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|                            | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered empty.       | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                            | (b) (4)               |                      |
| User entered '03 Mar 2021' | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|                            | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered '0'          | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|                           | (b) (4)               |                      |



US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'Yes (Y)'    | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered empty.       | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Karol Moore (b) (4)   | 29 Mar 2021 23:00:59 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '3' | System | 29 Mar 2021 23:00:59 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Mar 2021 23:00:59 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 29 Mar 2021 23:00:59 |

US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:03:25

[Name of Medication](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| User signature succeeded.   | Carlos Fierro (b) (4)                      | 06 Apr 2021 02:47:03 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 29 Mar 2021 23:03:21 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)            | 29 Mar 2021 23:03:21 |
| Data point term sent to Coder   | System                                     | 29 Mar 2021 23:02:25 |
| User entered 'FLUOXETINE'   | Karol Moore (b) (4)<br>(b) (4)             | 29 Mar 2021 23:02:15 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Prophylaxis](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|                           | (b) (4)               |                      |



US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Indication](#)

| Audit                                     | User                  | Time (GMT)           |
|---|-----------------------|----------------------|
| User signature succeeded.                 | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|   | (b) (4)               |                      |
| User entered 'EXACERBATION OF DEPRESSION' | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|   | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose per administration](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered '40'         | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose unit](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'mg (mg)'    | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

If dose unit is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered empty.       | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Frequency](#)

| Audit                          | User                  | Time (GMT)           |
|--------------------------------|-----------------------|----------------------|
| User signature succeeded.      | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                                | (b) (4)               |                      |
| User entered 'once daily (QD)' | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|                                | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[If frequency is Other, specify](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered empty.       | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Route of administration](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                            | (b) (4)               |                      |
| User entered 'Oral (ORAL)' | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|                            | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

If route of administration is Other, specify

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered empty.       | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|                           | (b) (4)               |                      |



US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                  | Time (GMT)           |
|----------------------------|-----------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                            | (b) (4)               |                      |
| User entered '05 Mar 2021' | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|                            | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date completely unknown](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered '0'          | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Ongoing?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'Yes (Y)'    | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered empty.       | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Was this medication taken for solicited event?](#)

| Audit                     | User                  | Time (GMT)           |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
|                           | (b) (4)               |                      |
| User entered 'No (N)'     | Karol Moore (b) (4)   | 29 Mar 2021 23:02:15 |
|                           | (b) (4)               |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Mar 2021 23:02:15 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 29 Mar 2021 23:02:15 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 29 Mar 2021 23:02:15 |



US3312465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:03:25

[Name of Medication](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4) | 08 Apr 2021 16:15:49 |
|  | (b) (4)               |                      |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: PSYCHOANALEPTICS, ATC:<br>ANTIDEPRESSANTS, ATC: OTHER<br>ANTIDEPRESSANTS, PRODUCT: TRAZODONE<br>- version WHODrug-Global-B3\\202003. | Coder Import (b) (4)  | 08 Apr 2021 16:04:50 |
|  | (b) (4)               |                      |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)  | 08 Apr 2021 16:04:50 |
|  | (b) (4)               |                      |
| Data point term sent to Coder  | System                | 08 Apr 2021 16:03:23 |
| User entered 'trazadone'   | (b) (4), (b) (6)      | 08 Apr 2021 16:02:29 |
|  |                       |                      |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Indication](#)

| Audit                                     | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                 | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'exacerbation of depression' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '50'         | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Frequency](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| User signature succeeded.    | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'other (OTHER)' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'HS'         | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |



US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '02 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 08 Apr 2021 16:15:49 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Apr 2021 16:02:29 |



US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:03:25**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 08 Apr 2021 16:02:29 |

US3312465

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 17:03:25**

[Were any concomitant procedures performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 19 Feb 2021 15:40:10 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:24:36 |
| User entered<br>'USA-US300-2021-MRNA-1273-P301000021' | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Yes (Y)'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Death

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Yes (Y)'    | System                      | 29 Mar 2021 17:24:15 |



US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Carlos'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Fierro'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: [Street](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| User signature succeeded.         | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.              | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered '16300 College Blvd' | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: [City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Shawnee'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: [State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'KS'         | System                      | 29 Mar 2021 17:24:15 |



US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: Postal Code

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered '66219'      | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'US'         | System                      | 29 Mar 2021 17:24:43 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 16 Apr 2021 13:50:04 |
| User entered '3' | System | 09 Apr 2021 14:13:24 |
| User entered '2' | System | 01 Apr 2021 12:54:16 |
| User entered '1' | System | 29 Mar 2021 17:24:43 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:03:25**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:24:36 |
| User entered<br>'USA-US300-2021-MRNA-1273-P301000021' | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Yes (Y)'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Death

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:03:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Yes (Y)'    | System                      | 29 Mar 2021 17:24:15 |



US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Carlos'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Fierro'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: Street

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| User signature succeeded.         | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.              | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered '16300 College Blvd' | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: [City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Shawnee'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: State

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'KS'         | System                      | 29 Mar 2021 17:24:15 |



**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:03:25**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered '66219'      | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'US'         | System                      | 29 Mar 2021 17:24:43 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 16 Apr 2021 13:50:04 |
| User entered '3' | System | 09 Apr 2021 14:13:24 |
| User entered '2' | System | 01 Apr 2021 12:54:16 |
| User entered '1' | System | 29 Mar 2021 17:24:43 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:03:25**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| User signature succeeded.        | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered '29/Mar/2021 13:24' | (b) (4)<br>System     | 29 Mar 2021 17:24:43 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:03:25

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'I'          | (b) (4), (b) (6)            | 29 Mar 2021 17:24:43 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:03:25**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:24:36 |
| User entered<br>'USA-US300-2021-MRNA-1273-P301000021' | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Yes (Y)'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Death

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |



US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:03:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Yes (Y)'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Carlos'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Fierro'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: [Street](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| User signature succeeded.         | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.              | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered '16300 College Blvd' | System                      | 29 Mar 2021 17:24:15 |



US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: [City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Shawnee'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: [State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'KS'         | System                      | 29 Mar 2021 17:24:15 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:03:25**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered '66219'      | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'US'         | System                      | 29 Mar 2021 17:24:43 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 16 Apr 2021 13:50:04 |
| User entered '3' | System | 09 Apr 2021 14:13:24 |
| User entered '2' | System | 01 Apr 2021 12:54:16 |
| User entered '1' | System | 29 Mar 2021 17:24:43 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:03:25**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| User signature succeeded.        | Carlos Fierro (b) (4)  | 06 Apr 2021 02:47:03 |
|                                  | (b) (4)                |                      |
| User entered '31/Mar/2021 17:00' | Heather Barker (b) (4) | 31 Mar 2021 22:01:45 |
|                                  | (b) (4)                |                      |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:03:25

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 09 Apr 2021 14:12:43 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 12:54:16 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:24:36 |
| User entered<br>'USA-US300-2021-MRNA-1273-P301000021' | System                      | 29 Mar 2021 17:24:15 |



US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Yes (Y)'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Death

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Yes (Y)'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Carlos'     | System                      | 29 Mar 2021 17:24:15 |



US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Fierro'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: [Street](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| User signature succeeded.         | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.              | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered '16300 College Blvd' | System                      | 29 Mar 2021 17:24:15 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:03:25**

[Site Address: City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Shawnee'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: State

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'KS'         | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: Postal Code

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered '66219'      | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'US'         | System                      | 29 Mar 2021 17:24:43 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 16 Apr 2021 13:50:04 |
| User entered '3' | System | 09 Apr 2021 14:13:24 |
| User entered '2' | System | 01 Apr 2021 12:54:16 |
| User entered '1' | System | 29 Mar 2021 17:24:43 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:03:25**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| User signature succeeded.        | Carlos Fierro (b) (4) | 06 Apr 2021 02:47:03 |
| User entered '01/Apr/2021 05:54' | (b) (4)<br>System     | 01 Apr 2021 12:54:16 |



US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:03:25

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety.      | (b) (4), (b) (6)            | 09 Apr 2021 14:12:43 |
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 12:54:16 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:24:36 |
| User entered<br>'USA-US300-2021-MRNA-1273-P301000021' | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Yes (Y)'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Death

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:03:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Yes (Y)'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |



US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Carlos'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Fierro'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: [Street](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| User signature succeeded.         | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.              | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered '16300 College Blvd' | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: [City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Shawnee'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: State

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'KS'         | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: Postal Code

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered '66219'      | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'US'         | System                      | 29 Mar 2021 17:24:43 |



US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 16 Apr 2021 13:50:04 |
| User entered '3' | System | 09 Apr 2021 14:13:24 |
| User entered '2' | System | 01 Apr 2021 12:54:16 |
| User entered '1' | System | 29 Mar 2021 17:24:43 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:03:25**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| User signature succeeded.        | Carlos Fierro (b) (4) | 09 Apr 2021 15:59:36 |
| User entered '09/Apr/2021 10:13' | (b) (4)<br>System     | 09 Apr 2021 14:13:24 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:03:25

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 09 Apr 2021 15:59:36 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 09 Apr 2021 14:13:24 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:03:25**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:24:36 |
| User entered<br>'USA-US300-2021-MRNA-1273-P301000021' | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Serious

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Yes (Y)'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Death

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:03:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Yes (Y)'    | System                      | 29 Mar 2021 17:24:15 |



US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'No (N)'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Carlos'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Fierro'     | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: [Street](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| User signature succeeded.         | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.              | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered '16300 College Blvd' | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: [City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'Shawnee'    | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

Site Address: State

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'KS'         | System                      | 29 Mar 2021 17:24:15 |



**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:03:25**

[Site Address: Postal Code](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered '66219'      | System                      | 29 Mar 2021 17:24:15 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 17:03:25

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 06 Apr 2021 02:47:03 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 17:25:33 |
| User entered 'US'         | System                      | 29 Mar 2021 17:24:43 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:03:25**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '4' | System | 16 Apr 2021 13:50:04 |
| User entered '3' | System | 09 Apr 2021 14:13:24 |
| User entered '2' | System | 01 Apr 2021 12:54:16 |
| User entered '1' | System | 29 Mar 2021 17:24:43 |

**US3312465**

**Folder: SAE USA-US300-2021-MRNA-1273-P301000021**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:03:25**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                  | Time (GMT)           |
|----------------------------------|-----------------------|----------------------|
| User signature succeeded.        | Carlos Fierro (b) (4) | 22 Apr 2021 20:47:22 |
| User entered '16/Apr/2021 09:50' | (b) (4)<br>System     | 16 Apr 2021 13:50:04 |

US3312465

Folder: SAE USA-US300-2021-MRNA-1273-P301000021

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:03:25

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Carlos Fierro (b) (4)       | 22 Apr 2021 20:47:22 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 16 Apr 2021 13:50:04 |