

US3092245 (Prod: Global Medical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:10:08

All time stamps listed in this document are displayed in GMT

US3092245

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 03:47:19

Generated On: 09 Jun 2021 15:10:08

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[Participant ID](#)

US3092245

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

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US3092245

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 27 AUG 2020                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | SCRN                                    |

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 03:47:22

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 03:47:22

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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) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Apr 2021 02:23:41

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|   |  |
|---|--|
| Condition   | PARTIAL HYSTERECTOMY   |
| Start date (dd MMM yyyy)                          | UN UNK 2001  |
| 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 2001  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2001   |
| Start Year (derived)                              | 2001   |
| Stop Month and Year (derived)                     | JAN 2001   |
| Stop Year (derived)                               | 2001   |

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

|   |  |
|---|--|
| Condition   | POST MENOPAUSAL  |
| Start date (dd MMM yyyy)                          | UN UNK 2001  |
| 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 2001   |
| Start Year (derived)                              | 2001   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Apr 2021 02:23:41

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

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Form: Medical History (5)

Data signed: (b) (4) 29 Apr 2021 02:23:41

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|   |  |
|---|--|
| Condition   | SHINGLES   |
| Start date (dd MMM yyyy)                          | UN UNK 2017  |
| Start date completely unknown                     | False  |
| Condition ongoing at study entry                  | Yes <input type="radio"/><br>No <input checked="" type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | UN UNK 2017  |
| Stop date completely unknown                      | False  |
| Start Month and Year (derived)                    | JAN 2017   |
| Start Year (derived)                              | 2017   |
| Stop Month and Year (derived)                     | JAN 2017   |
| Stop Year (derived)                               | 2017   |

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Apr 2021 02:23:41

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|   |  |
|---|--|
| Condition   | UPPER LEFT TORSO PAIN<br>SECONDARY TO SHINGLES                   |
| Start date (dd MMM yyyy)                                | UN UNK 2017  |
| 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 2017   |
| Start Year (derived)                                    | 2017   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Apr 2021 02:23:41

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|   |  |
|---|--|
| Condition   | DEPRESSION   |
| Start date (dd MMM yyyy)                                | UN UNK 2017  |
| 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 2017   |
| Start Year (derived)                                    | 2017   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Apr 2021 02:23:41

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|   |  |
|---|--|
| Condition   | BILATERAL GLAUCOMA   |
| Start date (dd MMM yyyy)                          | UN UNK 2017  |
| 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 2017   |
| Start Year (derived)                              | 2017   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Apr 2021 02:23:41

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|   |  |
|---|--|
| Condition   | HYPERLIPIDEMIA   |
| Start date (dd MMM yyyy)                          | UN UNK 2017  |
| 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 2017   |
| Start Year (derived)                              | 2017   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 29 Apr 2021 02:23:41

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 29 Apr 2021 02:23:41

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|   |  |
|---|--|
| Condition   | OVERACTIVE BLADDER   |
| Start date (dd MMM yyyy)                                | UN JUN 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)                          | JUN 2020   |
| Start Year (derived)                                    | 2020   |
| Stop Month and Year (derived)                           | _____  |
| Stop Year (derived)                                     | _____  |

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 29 Apr 2021 02:23:41

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|   |  |
|---|--|
| Condition   | MUSCLE SPASMS BILATERAL<br>LEGS                                  |
| Start date (dd MMM yyyy)                          | UN UNK 2017  |
| 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 2017   |
| Start Year (derived)                              | 2017   |
| Stop Month and Year (derived)                     |  |
| Stop Year (derived)                               |  |

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

|   |  |
|---|--|
| Condition   | INTERMITTENT SHORTNESS OF BREATH                                 |
| 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: Vital Signs

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

|   |                                      |
|---|--------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/> |
|   | No <input type="radio"/>             |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 27 AUG 2020                          |
| Time of assessment ( <i>00:00-23:59</i> ) | 12:50 (24 HR)                        |
| Vital Signs Date and Time (derived)       | 27 AUG 2020 12:50                    |
| Height ( <i>xxx.x</i> )                   | 152.4 cm                             |
| Weight ( <i>xxx.x</i> )                   | 165.1 kg                             |
| BMI ( <i>xxx.x</i> )                      | 71.08486 kg/m <sup>2</sup>           |
| BMI units                                 | KG/M2                                |
| Temperature ( <i>xxx.x</i> )              | ND - Not Done                        |
| Route of measurement                      | Oral <input type="radio"/>           |
|   | Axillary <input type="radio"/>       |
|   | Other <input type="radio"/>          |
| If Other, specify                         |                                      |
| Pulse ( <i>xxx</i> )                      | ND - Not Done                        |
| Pulse units                               | BPM                                  |
| Respiratory Rate ( <i>xxx</i> )           | ND - Not Done                        |
| Respiratory Rate units                    | BREATHS/MIN                          |
| Systolic Blood Pressure ( <i>xxx</i> )    | ND - Not Done                        |
| Systolic Blood Pressure units             | MMHG                                 |
| Diastolic Blood Pressure ( <i>xxx</i> )   | ND - Not Done                        |
| Diastolic Blood Pressure units            | MMHG                                 |
| Height (derived)                          |                                      |
| Weight (derived)                          |                                      |

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:47:22

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 03:47:22

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Date of assessment (dd MMM yyyy) 27 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2001

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 03:47:22

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

---

**Specify**

---

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

**No Risk Identified** False

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



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 03:47:22

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

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

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

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

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 03:47:22

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

What was the participant's randomization number? 188546

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 03:47:48

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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) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| Timepoint                           | Pre-Dose <input checked="" type="radio"/><br>Post-Dose <input type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 27 AUG 2020  |
| Time of assessment (00:00-23:59)    | 12:50 (24 HR)  |
| Vital Signs Date and Time (derived) | 27 AUG 2020 12:50  |
| Temperature (xxx.x)                 | 98.2 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 77 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 164 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 76 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

|                                     |  |
|-------------------------------------|--|
| Height                              | ND - Not Done  |
| Weight                              | ND - Not Done  |
| Timepoint                           | Pre-Dose <input type="radio"/><br>Post-Dose <input checked="" type="radio"/>                           |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/><br>No <input type="radio"/>                                       |
| Date of assessment (dd MMM yyyy)    | 27 AUG 2020  |
| Time of assessment (00:00-23:59)    | 14:24 (24 HR)  |
| Vital Signs Date and Time (derived) | 27 AUG 2020 14:24  |
| Temperature (xxx.x)                 | 97.3 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify                   |  |
| Pulse (xxx)                         | 76 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 138 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: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:47:22

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Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 03:47:22

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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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 13:50 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 13:50

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) 23 Feb 2021 03:47:22

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|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 27 AUG 2020                          |
| Collection time (00:00-23:59)      | 13:43 (24 HR)                        |
| Collection date and time (derived) | 27 AUG 2020 13:43                    |

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 27 AUG 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 13:39                           | 27 AUG 2020 13:39                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3092245

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**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 97.3 °F

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

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

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

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

PC Time Stamp 27 AUG 2020 14:30

PC Open Date & Time 27 AUG 2020 14:10

PC Close Date & Time 27 AUG 2020 16:40

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**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 97.6 °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):

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

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

PC Time Stamp 27 AUG 2020 23:38

PC Open Date & Time 27 AUG 2020 17:35

PC Close Date & Time 28 AUG 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

28 AUG 2020 15:20

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 16:50

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**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

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

31 AUG 2020 06:56

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59



US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:52

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**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

98.6 °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

01 SEP 2020 13:52

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**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 98.7 °F

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

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

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

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

PC Time Stamp 02 SEP 2020 15:58

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 9

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

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

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

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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

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 14:31

PC Open Date & Time

27 AUG 2020 14:10

PC Close Date & Time

27 AUG 2020 16:40

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 23:39

PC Open Date & Time

27 AUG 2020 17:35

PC Close Date & Time

28 AUG 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 15:21

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59



US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 16:51

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 06:57

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:53

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 13:53

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 15:59

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**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 ☐

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 27 AUG 2020 14:32 |
| PC Open Date & Time  | 27 AUG 2020 14:10 |
| PC Close Date & Time | 27 AUG 2020 16:40 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**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 ☐



US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 28 AUG 2020 08:51 |
| PC Open Date & Time  | 27 AUG 2020 17:35 |
| PC Close Date & Time | 28 AUG 2020 11:59 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**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 ☒

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 28 AUG 2020 15:24 |
| PC Open Date & Time          | 28 AUG 2020 12:00 |
| PC Close Date & Time         | 29 AUG 2020 11:59 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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 ☒

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 29 AUG 2020 16:53 |
| PC Open Date & Time          | 29 AUG 2020 12:00 |
| PC Close Date & Time         | 30 AUG 2020 11:59 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 31 AUG 2020 06:58 |
| PC Open Date & Time          | 30 AUG 2020 12:00 |
| PC Close Date & Time         | 31 AUG 2020 11:59 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

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 ☒



US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 31 AUG 2020 13:02 |
| PC Open Date & Time          | 31 AUG 2020 12:00 |
| PC Close Date & Time         | 01 SEP 2020 11:59 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

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 ☒

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 01 SEP 2020 13:54 |
| PC Open Date & Time          | 01 SEP 2020 12:00 |
| PC Close Date & Time         | 02 SEP 2020 11:59 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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 ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 02 SEP 2020 16:01 |
| PC Open Date & Time          | 02 SEP 2020 12:00 |
| PC Close Date & Time         | 03 SEP 2020 11:59 |

US3092245

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time Stamp

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3092245

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 15:10:08

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time Stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 15:10:08

TIMEPOINT

DAY 8

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

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 15:10:08

TIMEPOINT

DAY 9

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

**ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 8

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

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 15:10:08

TIMEPOINT

DAY 9

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

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3092245

Folder: Diary Dose 1 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 15:10:08

---

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of **CHILLS** you  
are experiencing

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

---

PC Open Date & Time

03 SEP 2020 12:00

---

PC Close Date & Time

04 SEP 2020 11:59

---

PC Time stamp

---

US3092245

Folder: Diary Dose 1 (1)

Form: Chills\_Day(9)

Generated On: 09 Jun 2021 15:10:08

---

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of **CHILLS** you  
are experiencing

None ☐

No interference with activity ☐

Some interference with activity ☐  
not requiring medical attention

Prevents daily activity and ☐  
requires medical attention

---

PC Open Date & Time

04 SEP 2020 12:00

---

PC Close Date & Time

05 SEP 2020 11:59

---

PC Time stamp

---

US3092245

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:10:08

|   |                              |
|---|------------------------------|
| <b>TIMEPOINT</b>  | DAY 8                        |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input type="checkbox"/>  |
|   | Yes <input type="checkbox"/> |
| PC Time stamp   |                              |
| PC Open Date & Time   | 03 SEP 2020 12:00            |
| PC Close Date & Time  | 04 SEP 2020 11:59            |



US3092245

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 15:10:08

|   |                              |
|---|------------------------------|
| <b>TIMEPOINT</b>  | DAY 9                        |
| Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms? | No <input type="checkbox"/>  |
|   | Yes <input type="checkbox"/> |
| PC Time stamp   |                              |
| PC Open Date & Time   | 04 SEP 2020 12:00            |
| PC Close Date & Time  | 05 SEP 2020 11:59            |

US3092245

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT VM

*If Contact Not Made, please provide Comments*

US3092245

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092245

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

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

US3092245

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 29 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                                  |



US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

|                                     |   |
|-------------------------------------|---|
| 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)    | 29 SEP 2020                               |
| Time of assessment (00:00-23:59)    | 13:54 (24 HR)                             |
| Vital Signs Date and Time (derived) | 29 SEP 2020 13:54                         |
| Temperature (xxx.x)                 | 36.1 C                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 66 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 15 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 158 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 72 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

|                                     |  |
|-------------------------------------|--|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>       |
|                                     | No <input type="radio"/>                   |
| Date of assessment (dd MMM yyyy)    | 29 SEP 2020                                |
| Time of assessment (00:00-23:59)    | 15:00 (24 HR)                              |
| Vital Signs Date and Time (derived) | 29 SEP 2020 15:00                          |
| Temperature (xxx.x)                 | 98.8 F                                     |
| Route of measurement                | Oral <input checked="" type="radio"/>      |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |  |
| Pulse (xxx)                         | 78 beats/min                               |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 138 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 84 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3092245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 14:28 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 14:28

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

US3092245

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 29 SEP 2020                          |
| Collection time (00:00-23:59)      | 14:25 (24 HR)                        |
| Collection date and time (derived) | 29 SEP 2020 14:25                    |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 31 Mar 2021 16:41:20

Generated On: 09 Jun 2021 15:10:08

|                               |                           |                                 |                                    |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) |                           |                                 | 29 SEP 2020                        |
| Lab Test                      | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1         | Yes                       | 14:20                           | 29 SEP 2020 14:20                  |
| Nasopharyngeal Swab 2         | No                        |                                 |                                    |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**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

98.8 °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

29 SEP 2020 14:57

PC Open Date & Time

29 SEP 2020 14:48

PC Close Date & Time

29 SEP 2020 17:18



US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**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 98.5 °F

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 29 SEP 2020 22:39 |
| PC Open Date & Time  | 29 SEP 2020 18:13 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

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

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

PC Time Stamp 01 OCT 2020 00:01

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**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 98.3 °F

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

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

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

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

PC Time Stamp 01 OCT 2020 21:50

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

|  |                                      |
|--|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 97.8 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 02 OCT 2020 12:01 |
| PC Open Date & Time  | 02 OCT 2020 12:00 |
| PC Close Date & Time | 03 OCT 2020 11:59 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

|  |                                      |
|--|--------------------------------------|
| Was <b>TEMPERATURE</b> taken?                            | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Please record your <b>TEMPERATURE</b> in °F              | 98.3 °F                              |
| Was any <b>MEDICATION TAKEN</b> today for pain or fever? | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |

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

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

|                      |                   |
|----------------------|-------------------|
| PC Time Stamp        | 03 OCT 2020 14:02 |
| PC Open Date & Time  | 03 OCT 2020 12:00 |
| PC Close Date & Time | 04 OCT 2020 11:59 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**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

98.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

04 OCT 2020 12:02

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**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

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

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59



US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**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

29 SEP 2020 14:56

PC Open Date & Time

29 SEP 2020 14:48

PC Close Date & Time

29 SEP 2020 17:18

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**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

29 SEP 2020 22:40

PC Open Date & Time

29 SEP 2020 18:13

PC Close Date & Time

30 SEP 2020 11:59

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**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 00:01

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**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

01 OCT 2020 21:51

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**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

02 OCT 2020 12:02

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**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

03 OCT 2020 14:03

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**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

04 OCT 2020 12:03

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**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 ☐

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



US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**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 ☐

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 29 SEP 2020 14:56 |
| PC Open Date & Time  | 29 SEP 2020 14:48 |
| PC Close Date & Time | 29 SEP 2020 17:18 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**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 ☐

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

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

No ☒

Yes ☐

|                      |                   |
|----------------------|-------------------|
| PC Time stamp        | 29 SEP 2020 22:41 |
| PC Open Date & Time  | 29 SEP 2020 18:13 |
| PC Close Date & Time | 30 SEP 2020 11:59 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 01 OCT 2020 00:03 |
| PC Open Date & Time          | 30 SEP 2020 12:00 |
| PC Close Date & Time         | 01 OCT 2020 11:59 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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  
EAB) (1725)

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US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 01 OCT 2020 21:52 |
| PC Open Date & Time          | 01 OCT 2020 12:00 |
| PC Close Date & Time         | 02 OCT 2020 11:59 |



US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

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

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

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 ☒

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 03 OCT 2020 14:04 |
| PC Open Date & Time          | 03 OCT 2020 12:00 |
| PC Close Date & Time         | 04 OCT 2020 11:59 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

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 ☒

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

|                              |                   |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> |                   |
| PC Time stamp                | 04 OCT 2020 12:03 |
| PC Open Date & Time          | 04 OCT 2020 12:00 |
| PC Close Date & Time         | 05 OCT 2020 11:59 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**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 ☐

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

Yes ☐

PC Time stamp

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59



US3092245

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 15:10:08

TIMEPOINT

DAY 8

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

None ☐

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3092245

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 15:10:08

TIMEPOINT

DAY 8

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

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3092245

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:10:08

|   |                              |
|---|------------------------------|
| <b>TIMEPOINT</b>  | DAY 8                        |
| Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms? | No <input type="checkbox"/>  |
|   | Yes <input type="checkbox"/> |
| PC Time stamp   |                              |
| PC Open Date & Time   | 06 OCT 2020 12:00            |
| PC Close Date & Time  | 07 OCT 2020 11:59            |

US3092245

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092245

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092245

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3092245

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 20 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                                  |

US3092245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 20 OCT 2020                           |
| Time of assessment (00:00-23:59)    | 13:30 (24 HR)                         |
| Vital Signs Date and Time (derived) | 20 OCT 2020 13:30                     |
| Temperature (xxx.x)                 | 98.2 F                                |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 80 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 15 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 160 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 67 mmHg                               |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |

US3092245

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 OCT 2020

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

US3092245

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 OCT 2020

Collection time (00:00-23:59)

14:00 (24 HR)

Collection date and time (derived)

20 OCT 2020 14:00

US3092245

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:48

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59



US3092245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| TIMEPOINT   | DAY 71  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq$ 100.4°F/38°C)   | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3092245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| TIMEPOINT   | DAY 78  |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq$ 100.4°F/38°C)   | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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 checked="" type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission   | 24 NOV 2020 11:11:18   |
| Patient Cloud Open Date & Time  | 21 NOV 2020 00:01  |
| Patient Cloud Close Date & Time   | 25 NOV 2020 23:59  |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2020 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| TIMEPOINT   | DAY 103  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission   | 07 DEC 2020 09:51:19   |
| Patient Cloud Open Date & Time  | 05 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 09 DEC 2020 23:59  |



US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 14:10:00

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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

23 DEC 2020 12:09:05

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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   | 28 DEC 2020 12:01:25   |
| Patient Cloud Open Date & Time  | 26 DEC 2020 00:01  |
| Patient Cloud Close Date & Time   | 30 DEC 2020 23:59  |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| TIMEPOINT   | DAY 131  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Fever (Temperature $\geq$ 100.4°F/38°C)   | False  |
| Chills  | False  |
| Cough   | True   |
| Shortness of breath   | False  |
| Difficulty breathing  | False  |
| Fatigue   | False  |
| Muscle aches  | False  |
| Body aches  | False  |
| Headache  | False  |
| New loss of taste   | False  |
| New loss of smell   | False  |
| Sore throat   | False  |
| Congestion  | False  |
| Runny nose  | False  |
| Nausea  | False  |
| Vomiting  | False  |
| Diarrhea  | False  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission   | 04 JAN 2021 18:12:56   |
| Patient Cloud Open Date & Time  | 02 JAN 2021 00:01  |
| PRODUCTION RELEASE (v12.003<br>EAB) (1725)  |  |
| 155 of 2794   |  |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 12:54:15

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| TIMEPOINT   | DAY 145   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 08:36:30

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 11:42:11

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 166  |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 06 FEB 2021 22:13:05   |
| Patient Cloud Open Date & Time  | 06 FEB 2021 00:01  |
| Patient Cloud Close Date & Time   | 10 FEB 2021 23:59  |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 08:57:25

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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

23 FEB 2021 19:23:43

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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

02 MAR 2021 22:29:16

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| TIMEPOINT   | DAY 194  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Date and time of submission   | 09 MAR 2021 09:24:58   |
| Patient Cloud Open Date & Time  | 06 MAR 2021 00:01  |
| Patient Cloud Close Date & Time   | 10 MAR 2021 23:59  |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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

15 MAR 2021 15:41:08

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59



US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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

24 MAR 2021 11:45:16

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

|   |  |
|---|--|
| <b>TIMEPOINT</b>  | DAY 215  |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input 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   | 29 MAR 2021 12:02:56   |
| Patient Cloud Open Date & Time  | 27 MAR 2021 00:01  |
| Patient Cloud Close Date & Time   | 31 MAR 2021 23:59  |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 00:02:41

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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

13 APR 2021 20:12:04

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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

19 APR 2021 12:02:12

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| TIMEPOINT   | DAY 243  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input checked="" type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |  |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input checked="" type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission   | 28 APR 2021 10:47:20   |
| Patient Cloud Open Date & Time  | 24 APR 2021 00:01  |
| Patient Cloud Close Date & Time   | 28 APR 2021 23:59  |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| TIMEPOINT   | DAY 250   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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01 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59



US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 05 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 09 JUN 2021 23:59 |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 12 JUN 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 16 JUN 2021 23:59 |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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



US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59



US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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31 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐  
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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 362

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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18 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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°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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 SEP 2021 23:59 |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 02 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 06 OCT 2021 23:59 |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 16 OCT 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 20 OCT 2021 23:59 |



US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 13 NOV 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 17 NOV 2021 23:59 |



US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 04 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 08 DEC 2021 23:59 |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 11 DEC 2021 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 15 DEC 2021 23:59 |



US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Open Date & Time](#)

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18 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 495

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>  | 05 FEB 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 09 FEB 2022 23:59 |



US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 544

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
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|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 19 FEB 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 23 FEB 2022 23:59 |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Open Date & Time](#)

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19 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| TIMEPOINT   | DAY 586   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Close Date & Time](#)

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06 APR 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Open Date & Time](#)

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16 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 APR 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

|   |  |
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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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| <a href="#">Patient Cloud Open Date &amp; Time</a> | 23 APR 2022 00:01 |
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| <a href="#">Patient Cloud Close Date &amp; Time</a> | 27 APR 2022 23:59 |
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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>  |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59



US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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14 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>  |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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°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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐ 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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 25 JUN 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 29 JUN 2022 23:59 |



US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Close Date & Time](#)

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06 JUL 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>  |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

|   |                   |
|---|-------------------|
| Date and time of submission                         |                   |
| <a href="#">Patient Cloud Open Date &amp; Time</a>  | 09 JUL 2022 00:01 |
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 13 JUL 2022 23:59 |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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23 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUL 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 17 AUG 2022 23:59 |
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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

|   |  |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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> | 20 AUG 2022 00:01 |
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|   |                   |
|---|-------------------|
| <a href="#">Patient Cloud Close Date &amp; Time</a> | 24 AUG 2022 23:59 |
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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| TIMEPOINT   | DAY 733   |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?                               | No <input type="radio"/><br>Yes <input type="radio"/>   |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply):   |   |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )  | <input type="checkbox"/>  |
| Chills  | <input type="checkbox"/>  |
| Cough   | <input type="checkbox"/>  |
| Shortness of breath   | <input type="checkbox"/>  |
| Difficulty breathing  | <input type="checkbox"/>  |
| Fatigue   | <input type="checkbox"/>  |
| Muscle aches  | <input type="checkbox"/>  |
| Body aches  | <input type="checkbox"/>  |
| Headache  | <input type="checkbox"/>  |
| New loss of taste   | <input type="checkbox"/>  |
| New loss of smell   | <input type="checkbox"/>  |
| Sore throat   | <input type="checkbox"/>  |
| Congestion  | <input type="checkbox"/>  |
| Runny nose  | <input type="checkbox"/>  |
| Nausea  | <input type="checkbox"/>  |
| Vomiting  | <input type="checkbox"/>  |
| Diarrhea  | <input type="checkbox"/>  |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.                       | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="radio"/><br>Yes <input type="radio"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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°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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐ 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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

01 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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08 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2022 23:59

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US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

**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 ☐

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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



US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| TIMEPOINT   | DAY 789  |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?  | No <input type="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"/>  |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

| 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"/>   |

**US3092245**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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29 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2022 23:59

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US3092245

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:10:08

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No  |  | 27 FEB 2021 11:17:28      |

US3092245

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092245

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

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*



US3092245

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

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*

US3092245

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Mar 2021 18:32:02

Generated On: 09 Jun 2021 15:10:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092245

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Mar 2021 18:32:02

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 01:03:51

Generated On: 09 Jun 2021 15:10:08

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 07 APR 2021                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | VISIT4                                  |

US3092245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 01:03:51

Generated On: 09 Jun 2021 15:10:08

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>  |
|                                     | No <input type="radio"/>              |
| Date of assessment (dd MMM yyyy)    | 07 APR 2021                           |
| Time of assessment (00:00-23:59)    | 10:55 (24 HR)                         |
| Vital Signs Date and Time (derived) | 07 APR 2021 10:55                     |
| Temperature (xxx.x)                 | 98.7 F                                |
| Route of measurement                | Oral <input checked="" type="radio"/> |
|                                     | Axillary <input type="radio"/>        |
|                                     | Other <input type="radio"/>           |
| If Other, specify                   |                                       |
| Pulse (xxx)                         | 92 beats/min                          |
| Pulse units                         | BPM                                   |
| Respiratory Rate (xxx)              | 18 breaths/min                        |
| Respiratory Rate units              | BREATHS/MIN                           |
| Systolic Blood Pressure (xxx)       | 132 mmHg                              |
| Systolic Blood Pressure units       | MMHG                                  |
| Diastolic Blood Pressure (xxx)      | 76 mmHg                               |
| Diastolic Blood Pressure units      | MMHG                                  |
| Height (derived)                    |                                       |
| Weight (derived)                    |                                       |

US3092245

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 01:03:51

Generated On: 09 Jun 2021 15:10:08

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Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

07 APR 2021

---

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

---



US3092245

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 01:03:51

Generated On: 09 Jun 2021 15:10:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 APR 2021

Collection time (00:00-23:59)

11:39 (24 HR)

Collection date and time (derived)

07 APR 2021 11:39

US3092245

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 14 Apr 2021 01:03:51

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092245

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3092245**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

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*

**US3092245**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3092245

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:10:08

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

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3092245

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

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

|                          |            |
|--------------------------|------------|
| Visit date (dd MMM yyyy) | 9 FEB 2021 |
|--------------------------|------------|

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

|            |               |
|------------|---------------|
| Folder OID | UNBLND_DECIDE |
|------------|---------------|

US3092245

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 22:52:09

Generated On: 09 Jun 2021 15:10:08

|   |   |
|---|---|
| Date of updated informed consent ( <i>dd MMM yyyy</i> )               | 9 FEB 2021  |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | False   |
| Was the participant unblinded?  | Yes <input checked="" type="radio"/><br>No <input type="radio"/>  |
| Under what version of the Protocol was the Participant unblinded?     | Amendment 5 <input type="radio"/><br>Amendment 6 or later <input checked="" type="radio"/>                            |
| Date of unblinding ( <i>dd MMM yyyy</i> )                             | 9 FEB 2021  |
| Participant randomization assignment                                  | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/>   |
| Actual Dose 1   | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/><br>Not Administered <input type="radio"/> |
| Actual Dose 2   | mRNA-1273 <input type="radio"/><br>Placebo <input checked="" type="radio"/><br>Not Administered <input type="radio"/> |
| Will participant receive mRNA-1273?                                   | Yes <input checked="" type="radio"/><br>No <input type="radio"/>  |
| Placebo Only Flag   | 1   |
| Continuing with mRNA-1273   | 1   |

US3092245

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

|             |          |
|-------------|----------|
| Height      | 152.4 cm |
| Weight      | 383.6 lb |
| BMI (xxx.x) | 75.07338 |

US3092245

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

|                                     |  |
|-------------------------------------|--|
| Height                              | 152.4 cm   |
| Weight                              | 383.6 lb   |
| BMI (xxx.x)                         | 75.07338   |
| 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)    | 9 FEB 2021   |
| Time of assessment (00:00-23:59)    | 14:17 (24 HR)  |
| Vital Signs Date and Time (derived) | 9 FEB 2021 14:17   |
| Temperature (xxx.x)                 | 97.2 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify _____             |  |
| Pulse (xxx)                         | 84 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 15 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 150 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 90 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3092245

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

|                                     |  |
|-------------------------------------|--|
| Height                              | 152.4 cm   |
| Weight                              | 383.6 lb   |
| BMI (xxx.x)                         | 75.07338   |
| 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)    | 9 FEB 2021   |
| Time of assessment (00:00-23:59)    | 15:38 (24 HR)  |
| Vital Signs Date and Time (derived) | 9 FEB 2021 15:38   |
| Temperature (xxx.x)                 | 97.4 F   |
| Route of measurement                | Oral <input checked="" type="radio"/><br>Axillary <input type="radio"/><br>Other <input type="radio"/> |
| If Other, specify _____             |  |
| Pulse (xxx)                         | 89 beats/min   |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 16 breaths/min   |
| Respiratory Rate units              | BREATHS/MIN  |
| Systolic Blood Pressure (xxx)       | 154 mmHg   |
| Systolic Blood Pressure units       | MMHG   |
| Diastolic Blood Pressure (xxx)      | 94 mmHg  |
| Diastolic Blood Pressure units      | MMHG   |

US3092245

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

9 FEB 2021

---

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

---

US3092245

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 9 FEB 2021

What was the treatment time? (00:00-23:59) 14:57 (24 HR)

Treatment Date and Time (derived) 9 FEB 2021 14:57

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

US3092245

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 9 FEB 2021                           |
| Collection time (00:00-23:59)      | 14:54 (24 HR)                        |
| Collection date and time (derived) | 9 FEB 2021 14:54                     |



US3092245

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 9 FEB 2021                           |
| Collection time (00:00 - 23:59)    | 14:52                                |
| Collection Date and Time (derived) | 9 FEB 2021 14:52                     |

US3092245

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:21

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3092245

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 03:47:22

Generated On: 09 Jun 2021 15:10:08

|  |                                      |
|--|--------------------------------------|
| Is the participant continuing to the next visit? | Yes <input checked="" type="radio"/> |
|  | No <input type="radio"/>             |
| Continuing Flag                                  | 1                                    |
| OLD29 Placebo Flag                               | 1                                    |

US3092245

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 22:52:09

Generated On: 09 Jun 2021 15:10:08

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 09 MAR 2021                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | OLD29                                   |

US3092245

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Mar 2021 22:52:09

Generated On: 09 Jun 2021 15:10:08

|                                     |   |
|-------------------------------------|---|
| 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)    | 09 MAR 2021                               |
| Time of assessment (00:00-23:59)    | 14:46 (24 HR)                             |
| Vital Signs Date and Time (derived) | 09 MAR 2021 14:46                         |
| Temperature (xxx.x)                 | 97.3 F                                    |
| Route of measurement                | Oral <input checked="" type="radio"/>     |
|                                     | Axillary <input type="radio"/>            |
|                                     | Other <input type="radio"/>               |
| If Other, specify                   |   |
| Pulse (xxx)                         | 72 beats/min                              |
| Pulse units                         | BPM                                       |
| Respiratory Rate (xxx)              | 15 breaths/min                            |
| Respiratory Rate units              | BREATHS/MIN                               |
| Systolic Blood Pressure (xxx)       | 129 mmHg                                  |
| Systolic Blood Pressure units       | MMHG                                      |
| Diastolic Blood Pressure (xxx)      | 71 mmHg                                   |
| Diastolic Blood Pressure units      | MMHG                                      |

US3092245

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Mar 2021 22:52:09

Generated On: 09 Jun 2021 15:10:08

|                                     |  |
|-------------------------------------|--|
| Timepoint                           | Pre-Dose <input type="radio"/>             |
|                                     | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed?          | Yes <input checked="" type="radio"/>       |
|                                     | No <input type="radio"/>                   |
| Date of assessment (dd MMM yyyy)    | 09 MAR 2021                                |
| Time of assessment (00:00-23:59)    | 15:26 (24 HR)                              |
| Vital Signs Date and Time (derived) | 09 MAR 2021 15:26                          |
| Temperature (xxx.x)                 | 97.8 F                                     |
| Route of measurement                | Oral <input checked="" type="radio"/>      |
|                                     | Axillary <input type="radio"/>             |
|                                     | Other <input type="radio"/>                |
| If Other, specify                   |  |
| Pulse (xxx)                         | 74 beats/min                               |
| Pulse units                         | BPM  |
| Respiratory Rate (xxx)              | 18 breaths/min                             |
| Respiratory Rate units              | BREATHS/MIN                                |
| Systolic Blood Pressure (xxx)       | 134 mmHg                                   |
| Systolic Blood Pressure units       | MMHG                                       |
| Diastolic Blood Pressure (xxx)      | 69 mmHg                                    |
| Diastolic Blood Pressure units      | MMHG                                       |

US3092245

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 22:52:09

Generated On: 09 Jun 2021 15:10:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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



US3092245

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Mar 2021 22:52:09

Generated On: 09 Jun 2021 15:10:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 09 MAR 2021

What was the treatment time? (00:00-23:59) 14:56 (24 HR)

Treatment Date and Time (derived) 09 MAR 2021 14:56

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

US3092245

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 22:52:09

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 22:52:09

Generated On: 09 Jun 2021 15:10:08

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 MAR 2021

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

Comments 1ST ATTEMPT MADE ON  
03/16/21

If Contact Not Made, please provide Comments  
2ND ATTEMPT MADE ON  
03/17/21

US3092245

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 22:52:09

Generated On: 09 Jun 2021 15:10:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3092245

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Apr 2021 01:03:51

Generated On: 09 Jun 2021 15:10:08

|   |   |
|---|---|
| Was this visit performed?                                       | Yes <input checked="" type="radio"/>    |
|   | No <input type="radio"/>                |
| Visit date (dd MMM yyyy)  | 07 APR 2021                             |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/>              |
|   | Clinic <input checked="" type="radio"/> |
| Folder OID  | OLD57                                   |

US3092245

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Apr 2021 01:03:51

Generated On: 09 Jun 2021 15:10:08

|   |                                       |
|---|---------------------------------------|
| Were vital signs assessed?                | Yes <input checked="" type="radio"/>  |
|   | No <input type="radio"/>              |
| Date of assessment ( <i>dd MMM yyyy</i> ) | 07 APR 2021                           |
| Time of assessment ( <i>00:00-23:59</i> ) | 10:55 (24 HR)                         |
| Vital Signs Date and Time (derived)       | 07 APR 2021 10:55                     |
| Temperature ( <i>xxx.x</i> )              | 98.7 F                                |
| Route of measurement                      | Oral <input checked="" type="radio"/> |
|   | Axillary <input type="radio"/>        |
|   | Other <input type="radio"/>           |
| If Other, specify                         |                                       |
| Pulse ( <i>xxx</i> )                      | 92 beats/min                          |
| Pulse units                               | BPM                                   |
| Respiratory Rate ( <i>xxx</i> )           | 18 breaths/min                        |
| Respiratory Rate units                    | BREATHS/MIN                           |
| Systolic Blood Pressure ( <i>xxx</i> )    | 132 mmHg                              |
| Systolic Blood Pressure units             | MMHG                                  |
| Diastolic Blood Pressure ( <i>xxx</i> )   | 76 mmHg                               |
| Diastolic Blood Pressure units            | MMHG                                  |
| Height (derived)                          |                                       |
| Weight (derived)                          |                                       |

US3092245

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Apr 2021 01:03:51

Generated On: 09 Jun 2021 15:10:08

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

07 APR 2021

---

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

---

US3092245

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Apr 2021 01:03:51

Generated On: 09 Jun 2021 15:10:08

|                                    |                                      |
|------------------------------------|--------------------------------------|
| Was the sample collected?          | Yes <input checked="" type="radio"/> |
|                                    | No <input type="radio"/>             |
| Collection date (dd MMM yyyy)      | 07 APR 2021                          |
| Collection time (00:00-23:59)      | 11:39 (24 HR)                        |
| Collection date and time (derived) | 07 APR 2021 11:39                    |



US3092245

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 03:47:20

Generated On: 09 Jun 2021 15:10:08

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

AEID

Adverse event

MOTOR VEHICLE ACCIDENT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

21 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

|   |  |
|---|--|
| Congenital anomaly or birth defect        | False  |
| Other medically important event           | False  |
| Relationship to investigational product   | <div>Not Related <input checked="" type="radio"/></div> <div>Related <input type="radio"/></div> <div>Not Applicable <input type="radio"/></div>   |
| Relationship to Study Procedure           | <div>Not Related <input checked="" type="radio"/></div> <div>Related <input type="radio"/></div> <div>Not Applicable <input type="radio"/></div>   |
| Action taken with investigational product | <div>None <input type="radio"/></div> <div>Dose Delayed <input type="radio"/></div> <div>Investigational Product Withdrawn <input type="radio"/></div> <div>Not Applicable <input checked="" type="radio"/></div>  |
| Other action taken (check all that apply) |  |
| None                                      | True   |
| Concomitant Medication                    | False  |
| Concomitant Procedure                     | False  |
| Outcome                                   | <div>Fatal <input type="radio"/></div> <div>Not Recovered/Not Resolved <input type="radio"/></div> <div>Recovered/Resolved <input checked="" type="radio"/></div> <div>Recovered/Resolved with Sequelae <input type="radio"/></div> <div>Recovering/Resolving <input type="radio"/></div> <div>Unknown <input type="radio"/></div> |

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

|           |  |
|-----------|--|
| Narrative | SUBJECT STATES SHE IS STILL ADMITTED IN THE HOSPITAL. SHE STATES THAT SHE HAS LEFT SHOULDER, LEFT NECK AND LEFT ANKLE PAIN. BUT NO FRACTURES FROM THE MOTOR VEHICLE ACCIDENT. SUBJECT STATES THAT SHE WILL BE GOING TO REHAB FACILITY AFTER DISCHARGE FROM HOSPITAL. |
|-----------|--|

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

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

US3092245

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:10:08

AEID

Adverse event

MULTIPLE TRAUMAS DUE TO  
MOTOR VEHICLE ACCIDENT  
(LEFT SHOULDER, LEFT NECK  
AND LEFT ANKLE PAIN)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

21 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3092245

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:10:08

|  |   |
|--|---|
| 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 <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>   |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input type="radio"/><br>Recovered/Resolved with Sequelae <input type="radio"/><br>Recovering/Resolving <input checked="" type="radio"/><br>Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: |   |
| Narrative  |   |
| Serious Adverse Event Derived (CSA Programming Field Only)                   | 0   |
| Medically Attended AE Derived (CSA Programming Field Only)                   | 1   |
| Admitted to ICU Derived (CSA Programming Field Only)                         |   |

US3092245

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:10:08

|  |  |
|--|--|
| AEID   | USA-US086-2020-MRNA-1273-P30<br>1000007  |
| Adverse event  | CHEST PAIN TRAUMATIC DUE<br>TO MOTOR VEHICLE ACCIDENT  |
| 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)                                       | 21 NOV 2020  |
| Start time (00:00-23:59)                                       |  |
| AE start date and time (derived)                               |  |
| Ongoing?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| If not Ongoing, end date (dd MMM yyyy)                         | 25 NOV 2020  |
| End time (00:00-23:59)   |  |
| AE End Date and Time (derived)                                 |  |
| Severity   | Grade 1/Mild <input type="radio"/><br>Grade 2/Moderate <input checked="" type="radio"/><br>Grade 3/Severe <input 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)                          | 21 NOV 2020  |
| Hospital Discharge Date (dd MMM yyyy)                          | 25 NOV 2020  |
| Admitted to ICU?   | Yes <input type="radio"/><br>No <input checked="" type="radio"/><br>Unknown <input type="radio"/>  |
| Number of Days in ICU  |  |
| PRODUCTION RELEASE (v12.003<br>EAB) (1725)                     | 382 of 2794  |

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:10:08

|  |   |
|--|---|
| Persistent or significant disability or incapacity                           | False   |
| Congenital anomaly or birth defect   | False   |
| Other medically important event  | False   |
| Relationship to investigational product                                      | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Relationship to Study Procedure  | Not Related <input checked="" type="radio"/><br>Related <input type="radio"/><br>Not Applicable <input type="radio"/>   |
| Action taken with investigational product                                    | None <input type="radio"/><br>Dose Delayed <input type="radio"/><br>Investigational Product <input type="radio"/><br>Withdrawn <input type="radio"/><br>Not Applicable <input checked="" type="radio"/>   |
| Other action taken (check all that apply)                                    |   |
| None   | False   |
| Concomitant Medication   | True  |
| Concomitant Procedure  | False   |
| Outcome  | Fatal <input type="radio"/><br>Not Recovered/Not Resolved <input type="radio"/><br>Recovered/Resolved <input 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  |   |



US3092245

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:10:08

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SUBJECT STATES SHE WAS  
WAITING FOR HER HUSBAND  
TO PULL OUT THE CAR AND AS  
HE WAS BACKING OUT, HE DID  
NOT NOTICE HER AND WAS HIT  
WITH THE CAR. SHE REPORTS  
BEING HIT AND FALLING ON  
THE LEFT SIDE. AT THE ER, SHE  
STARTED HAVING SOME  
CHEST PAIN AND WAS  
ADMITTED WITH THE ABOVE  
DIAGNOSIS ON THE MEDICAL  
FLOOR. SHE WAS ADMITTED  
FOR PAIN MANAGEMENT,  
CHEST PAIN IMPROVED AND  
DETERMINED  
MUSCULOSKELETAL IN  
ETIOLOGY AND  
NON-CARDIAC. PHYSICAL  
THERAPY AND OCCUPATIONAL  
THERAPY.

---

|  |   |
|--|---|
| 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 |

---

US3092245

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:10:08

AEID

Adverse event

WORSENING OVERACTIVE  
BLADDER

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (9)

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

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 03:47:21

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Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:08

|                                |  |
|--------------------------------|--|
| Name of Medication             | SHINGLES VACCINE   |
| Prophylaxis                    | Yes <input checked="" type="radio"/><br>No <input type="radio"/>   |
| Indication                     | PROPHYLAXIS  |
| Dose per administration        | 1  |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input checked="" type="radio"/>   |
| If dose unit is Other, specify | INJECTION  |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input checked="" type="radio"/> |
| If frequency is Other, specify | YEARLY   |
| Route of administration        | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input checked="" type="radio"/>  |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:08

|                                |  |
|--------------------------------|--|
| Name of Medication             | LISINOPRIL/HCTZ  |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                     | HYPERTENSION   |
| Dose per administration        | 20/12.5  |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify |  |
| Frequency                      | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |  |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:08

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2015              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:08

|                                      |  |
|--------------------------------------|--|
| Name of Medication                   | AMLODIPINE   |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                           | HYPERTENSION   |
| Dose per administration              | 10   |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify _____ |  |
| Frequency                            | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |  |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2015              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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|                                      |   |
|--------------------------------------|---|
| Name of Medication                   | GABAPENTIN  |
| Prophylaxis                          | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>  |
| Indication                           | UPPER RIGHT TORSO PAIN<br>SECONDARY TO SHINGLES   |
| Dose per administration              | 600   |
| Dose unit                            | mg <input checked="" type="checkbox"/><br>ug <input type="checkbox"/><br>mL <input type="checkbox"/><br>g <input type="checkbox"/><br>IU <input type="checkbox"/><br>tablet <input type="checkbox"/><br>capsule <input type="checkbox"/><br>puff <input type="checkbox"/><br>Other <input type="checkbox"/>   |
| If dose unit is Other, specify _____ |   |
| Frequency                            | once daily <input type="checkbox"/><br>twice daily <input type="checkbox"/><br>three times daily <input type="checkbox"/><br>four times daily <input type="checkbox"/><br>every other day <input type="checkbox"/><br>every week <input type="checkbox"/><br>every month <input type="checkbox"/><br>as needed <input checked="" type="checkbox"/><br>once <input type="checkbox"/><br>unknown <input type="checkbox"/><br>other <input type="checkbox"/> |
| If frequency is Other, specify _____ |   |
| Route of administration              | Oral <input checked="" type="checkbox"/><br>Topical <input type="checkbox"/><br>Subcutaneous <input type="checkbox"/><br>Transdermal <input type="checkbox"/><br>Intraocular <input type="checkbox"/>   |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | UN UNK 2017                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   |                          | _____                            |
| Interval Dosage Unit Number (derived)              |                          | _____                            |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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|                                      |  |
|--------------------------------------|--|
| Name of Medication                   | SERTRALIN  |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                           | DEPRESSION   |
| Dose per administration              | 100  |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify _____ |  |
| Frequency                            | once daily <input checked="" type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |  |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2017              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:08

|                                |  |
|--------------------------------|--|
| Name of Medication             | TRAVATIN   |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                     | GLAUCOMA   |
| Dose per administration        | 1  |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input checked="" type="radio"/>   |
| If dose unit is Other, specify | DROP   |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input checked="" type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |  |
| Route of administration        | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input checked="" type="radio"/><br>Intramuscular <input type="radio"/>  |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2017              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____             |                          |                                  |
| Interval Dosage Unit Number (derived) _____        |                          |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:08

|                                      |   |
|--------------------------------------|---|
| Name of Medication                   | ATORVASTATIN  |
| Prophylaxis                          | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>  |
| Indication                           | HYPERCHOLESTEROLEMIA  |
| Dose per administration              | 40  |
| Dose unit                            | mg <input checked="" type="checkbox"/><br>ug <input type="checkbox"/><br>mL <input type="checkbox"/><br>g <input type="checkbox"/><br>IU <input type="checkbox"/><br>tablet <input type="checkbox"/><br>capsule <input type="checkbox"/><br>puff <input type="checkbox"/><br>Other <input type="checkbox"/>   |
| If dose unit is Other, specify _____ |   |
| Frequency                            | once daily <input checked="" type="checkbox"/><br>twice daily <input type="checkbox"/><br>three times daily <input type="checkbox"/><br>four times daily <input type="checkbox"/><br>every other day <input type="checkbox"/><br>every week <input type="checkbox"/><br>every month <input type="checkbox"/><br>as needed <input type="checkbox"/><br>once <input type="checkbox"/><br>unknown <input type="checkbox"/><br>other <input type="checkbox"/> |
| If frequency is Other, specify _____ |   |
| Route of administration              | Oral <input checked="" type="checkbox"/><br>Topical <input type="checkbox"/><br>Subcutaneous <input type="checkbox"/><br>Transdermal <input type="checkbox"/><br>Intraocular <input type="checkbox"/><br>Intramuscular <input type="checkbox"/>   |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2017              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   | 1                        |                                  |
| Interval Dosage Unit Number (derived)              | 1                        |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input checked="" type="radio"/> |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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|                                |   |
|--------------------------------|---|
| Name of Medication             | IBUPROFEN   |
| Prophylaxis                    | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>  |
| Indication                     | BILATERAL KNEE AND ANKLE PAIN   |
| Dose per administration        | 400   |
| Dose unit                      | mg <input checked="" type="checkbox"/><br>ug <input type="checkbox"/><br>mL <input type="checkbox"/><br>g <input type="checkbox"/><br>IU <input type="checkbox"/><br>tablet <input type="checkbox"/><br>capsule <input type="checkbox"/><br>puff <input type="checkbox"/><br>Other <input type="checkbox"/>   |
| If dose unit is Other, specify |   |
| Frequency                      | once daily <input type="checkbox"/><br>twice daily <input type="checkbox"/><br>three times daily <input type="checkbox"/><br>four times daily <input type="checkbox"/><br>every other day <input type="checkbox"/><br>every week <input type="checkbox"/><br>every month <input type="checkbox"/><br>as needed <input checked="" type="checkbox"/><br>once <input type="checkbox"/><br>unknown <input type="checkbox"/><br>other <input type="checkbox"/> |
| If frequency is Other, specify |   |
| Route of administration        | Oral <input checked="" type="checkbox"/><br>Topical <input type="checkbox"/><br>Subcutaneous <input type="checkbox"/><br>Transdermal <input type="checkbox"/><br>Intraocular <input type="checkbox"/>   |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | UN UNK 2015                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   |                          | _____                            |
| Interval Dosage Unit Number (derived)              |                          | _____                            |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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|                                      |  |
|--------------------------------------|--|
| Name of Medication                   | ALEVE  |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                           | BILATERAL KNEE PAIN  |
| Dose per administration              | 220  |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify _____ |  |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |  |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

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|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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"/>         |
| <hr/>  |                          |                                  |
| If route of administration is Other, specify <hr/> |                          |                                  |
| Start date (dd MMM yyyy)                           | UN UNK 2015              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| <hr/>  |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <hr/>       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| <hr/>  |                          |                                  |
| Separate Dosage Number (derived)                   | <hr/>                    |                                  |
| Interval Dosage Unit Number (derived)              | <hr/>                    |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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|                                      |  |
|--------------------------------------|--|
| Name of Medication                   | IBUPROFEN  |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                           | BODY/MUSCLE ACHES  |
| Dose per administration              | 400  |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify _____ |  |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |  |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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"/>            |
| <hr/>  |                          |                                     |
| If route of administration is Other, specify <hr/> |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 30 SEP 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| <hr/>  |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 4 OCT 2020                          |
| Was this medication taken for solicited event?     | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input type="checkbox"/>            |
| <hr/>  |                          |                                     |
| Separate Dosage Number (derived)                   |                          | <hr/>                               |
| Interval Dosage Unit Number (derived)              |                          | <hr/>                               |
| 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 (11)

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|                                      |  |
|--------------------------------------|--|
| Name of Medication                   | ALEVE  |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                           | BODY/MUSCLE ACHES  |
| Dose per administration              | 220  |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify _____ |  |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |  |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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|   |                          |                                     |
|---|--------------------------|-------------------------------------|
|   | 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"/>            |
| <hr/>   |                          |                                     |
| If route of administration is Other, specify <input type="text"/> |                          |                                     |
| <hr/>   |                          |                                     |
| Start date (dd MMM yyyy)  |                          | 30 SEP 2020                         |
| Start date completely unknown                                     |                          | False                               |
| Ongoing?  | Yes                      | <input type="checkbox"/>            |
|   | No                       | <input checked="" type="checkbox"/> |
| <hr/>   |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)                            |                          | 4 OCT 2020                          |
| <hr/>   |                          |                                     |
| Was this medication taken for solicited event?                    | Yes                      | <input checked="" type="checkbox"/> |
|   | No                       | <input type="checkbox"/>            |
| <hr/>   |                          |                                     |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>                |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>                |
| Interval Dosage Definition (derived)                              |                          | 802 <input type="checkbox"/>        |
|   |                          | 803 <input type="checkbox"/>        |
|   |                          | 804 <input type="checkbox"/>        |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

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|                                      |  |
|--------------------------------------|--|
| Name of Medication                   | TYLENOL  |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                           | BODY/MUSCLE ACHE   |
| Dose per administration              | 500  |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify _____ |  |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |  |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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"/>            |
| <hr/>  |                          |                                     |
| If route of administration is Other, specify <hr/> |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 30 SEP 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| <hr/>  |                          |                                     |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 4 OCT 2020                          |
| Was this medication taken for solicited event?     | Yes                      | <input checked="" type="checkbox"/> |
|  | No                       | <input type="checkbox"/>            |
| <hr/>  |                          |                                     |
| Separate Dosage Number (derived)                   |                          | <hr/>                               |
| Interval Dosage Unit Number (derived)              |                          | <hr/>                               |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input type="checkbox"/>            |

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Form: Prior/Concomitant Medication and Vaccination (13)

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|                                |  |
|--------------------------------|--|
| Name of Medication             | TRAMADOL   |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                     | MOTOR VEHICLE ACCIDENT   |
| Dose per administration        | UNKNOWN  |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input checked="" type="radio"/>   |
| If dose unit is Other, specify | UNKNOWN  |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |  |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

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|   |                          |                                  |
|---|--------------------------|----------------------------------|
|   | 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"/>         |
| <hr/>   |                          |                                  |
| If route of administration is Other, specify <input type="text"/> |                          |                                  |
| <hr/>   |                          |                                  |
| Start date (dd MMM yyyy)  |                          | 01 DEC 2020                      |
| Start date completely unknown                                     |                          | False                            |
| Ongoing?  | Yes                      | <input checked="" type="radio"/> |
|   | No                       | <input type="radio"/>            |
| <hr/>   |                          |                                  |
| If not Ongoing, End date (dd MMM yyyy) <input type="text"/>       |                          |                                  |
| <hr/>   |                          |                                  |
| Was this medication taken for solicited event?                    | Yes                      | <input type="radio"/>            |
|   | No                       | <input checked="" type="radio"/> |
| <hr/>   |                          |                                  |
| Separate Dosage Number (derived)                                  |                          | <input type="text"/>             |
| Interval Dosage Unit Number (derived)                             |                          | <input type="text"/>             |
| Interval Dosage Definition (derived)                              | 802                      | <input type="radio"/>            |
|   | 803                      | <input type="radio"/>            |
|   | 804                      | <input type="radio"/>            |

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Form: Prior/Concomitant Medication and Vaccination (14)

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|                                |  |
|--------------------------------|--|
| Name of Medication             | OXYBUTYNIN   |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                     | OVERACTIVE BLADDER   |
| Dose per administration        | 5  |
| Dose unit                      | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify |  |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input checked="" type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |  |
| Route of administration        | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input type="radio"/>  |

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|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | Respiratory (Inhalation) | <input type="checkbox"/>            |
|  | Intralesional            | <input type="checkbox"/>            |
|  | Intraperitoneal          | <input type="checkbox"/>            |
|  | Nasal                    | <input type="checkbox"/>            |
|  | Vaginal                  | <input type="checkbox"/>            |
|  | Rectal                   | <input type="checkbox"/>            |
|  | Intravenous              | <input type="checkbox"/>            |
|  | Intravenous Bolus        | <input type="checkbox"/>            |
|  | Intravenous Drip         | <input type="checkbox"/>            |
|  | Other                    | <input type="checkbox"/>            |
| If route of administration is Other, specify _____ |                          |                                     |
| Start date (dd MMM yyyy)                           |                          | 20 JUN 2020                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 09 MAR 2021                         |
| Was this medication taken for solicited event?     | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived)                   |                          | 2                                   |
| Interval Dosage Unit Number (derived)              |                          | 1                                   |
| Interval Dosage Definition (derived)               | 802                      | <input type="checkbox"/>            |
|  | 803                      | <input type="checkbox"/>            |
|  | 804                      | <input checked="" type="checkbox"/> |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:08

|                                      |  |
|--------------------------------------|--|
| Name of Medication                   | TYLENOL  |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                           | BACK KNEE PAIN<br>BACK ANKLE PAIN  |
| Dose per administration              | 500  |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify _____ |  |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |  |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/>   |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:08

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | Intramuscular            | <input type="checkbox"/>         |
|  | Respiratory (Inhalation) | <input type="checkbox"/>         |
|  | Intralesional            | <input type="checkbox"/>         |
|  | Intraperitoneal          | <input type="checkbox"/>         |
|  | Nasal                    | <input type="checkbox"/>         |
|  | Vaginal                  | <input type="checkbox"/>         |
|  | Rectal                   | <input type="checkbox"/>         |
|  | Intravenous              | <input type="checkbox"/>         |
|  | Intravenous Bolus        | <input type="checkbox"/>         |
|  | Intravenous Drip         | <input type="checkbox"/>         |
|  | Other                    | <input type="checkbox"/>         |
| If route of administration is Other, specify _____ |                          |                                  |
| Start date (dd MMM yyyy)                           |                          | UN UNK 2015                      |
| Start date completely unknown                      |                          | False                            |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived)                   |                          | _____                            |
| Interval Dosage Unit Number (derived)              |                          | _____                            |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:08

|                                |   |
|--------------------------------|---|
| Name of Medication             | AMITRIPTYLINE   |
| Prophylaxis                    | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>  |
| Indication                     | SLEEP AIDE FROM MVA DUE<br>TO PAIN LEFT UPPER AND<br>LOWER EXTREMITIES & LBP  |
| Dose per administration        | 25  |
| Dose unit                      | mg <input checked="" type="checkbox"/><br>ug <input type="checkbox"/><br>mL <input type="checkbox"/><br>g <input type="checkbox"/><br>IU <input type="checkbox"/><br>tablet <input type="checkbox"/><br>capsule <input type="checkbox"/><br>puff <input type="checkbox"/><br>Other <input type="checkbox"/>   |
| If dose unit is Other, specify |   |
| Frequency                      | once daily <input type="checkbox"/><br>twice daily <input type="checkbox"/><br>three times daily <input type="checkbox"/><br>four times daily <input type="checkbox"/><br>every other day <input type="checkbox"/><br>every week <input type="checkbox"/><br>every month <input type="checkbox"/><br>as needed <input checked="" type="checkbox"/><br>once <input type="checkbox"/><br>unknown <input type="checkbox"/><br>other <input type="checkbox"/> |
| If frequency is Other, specify |   |
| Route of administration        | Oral <input checked="" type="checkbox"/><br>Topical <input type="checkbox"/><br>Subcutaneous <input type="checkbox"/><br>Transdermal <input type="checkbox"/>   |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:08

|  |                          |                                  |
|--|--------------------------|----------------------------------|
|  | 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)                           | 19 JAN 2021              |                                  |
| Start date completely unknown                      | False                    |                                  |
| Ongoing?   | Yes                      | <input checked="" type="radio"/> |
|  | No                       | <input type="radio"/>            |
| If not Ongoing, End date (dd MMM yyyy) _____       |                          |                                  |
| Was this medication taken for solicited event?     | Yes                      | <input type="radio"/>            |
|  | No                       | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) _____             |                          |                                  |
| Interval Dosage Unit Number (derived) _____        |                          |                                  |
| Interval Dosage Definition (derived)               | 802                      | <input type="radio"/>            |
|  | 803                      | <input type="radio"/>            |
|  | 804                      | <input type="radio"/>            |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:08

|                                      |  |
|--------------------------------------|--|
| Name of Medication                   | TYLENOL 3<br>(CODEINE/ACETAMINOPHEN)   |
| Prophylaxis                          | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                           | SECONDARY/MOTOR VEHICLE<br>ACCIDENT  |
| Dose per administration              | 300  |
| Dose unit                            | mg <input checked="" type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input type="radio"/>   |
| If dose unit is Other, specify _____ |  |
| Frequency                            | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input checked="" type="radio"/><br>once <input type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify _____ |  |
| Route of administration              | Oral <input checked="" type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/>  |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:08

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           | 01 JAN 2021              |                                     |
| Start date completely unknown                      | False                    |                                     |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 14 JAN 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 (18)

Generated On: 09 Jun 2021 15:10:08

|                                |   |
|--------------------------------|---|
| Name of Medication             | CYCLOBENZAPRINE   |
| Prophylaxis                    | Yes <input type="checkbox"/><br>No <input checked="" type="checkbox"/>  |
| Indication                     | MUSCLE SPASMS BILATERAL<br>LEGS   |
| Dose per administration        | 10  |
| Dose unit                      | mg <input checked="" type="checkbox"/><br>ug <input type="checkbox"/><br>mL <input type="checkbox"/><br>g <input type="checkbox"/><br>IU <input type="checkbox"/><br>tablet <input type="checkbox"/><br>capsule <input type="checkbox"/><br>puff <input type="checkbox"/><br>Other <input type="checkbox"/>   |
| If dose unit is Other, specify |   |
| Frequency                      | once daily <input type="checkbox"/><br>twice daily <input type="checkbox"/><br>three times daily <input type="checkbox"/><br>four times daily <input type="checkbox"/><br>every other day <input type="checkbox"/><br>every week <input type="checkbox"/><br>every month <input type="checkbox"/><br>as needed <input checked="" type="checkbox"/><br>once <input type="checkbox"/><br>unknown <input type="checkbox"/><br>other <input type="checkbox"/> |
| If frequency is Other, specify |   |
| Route of administration        | Oral <input checked="" type="checkbox"/><br>Topical <input type="checkbox"/><br>Subcutaneous <input type="checkbox"/><br>Transdermal <input type="checkbox"/><br>Intraocular <input type="checkbox"/>   |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:08

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:08

|                                |  |
|--------------------------------|--|
| Name of Medication             | EPIDURAL STERIOD INJECTION   |
| Prophylaxis                    | Yes <input type="radio"/><br>No <input checked="" type="radio"/>   |
| Indication                     | OBESITY  |
| Dose per administration        | UNK  |
| Dose unit                      | mg <input type="radio"/><br>ug <input type="radio"/><br>mL <input type="radio"/><br>g <input type="radio"/><br>IU <input type="radio"/><br>tablet <input type="radio"/><br>capsule <input type="radio"/><br>puff <input type="radio"/><br>Other <input checked="" type="radio"/>   |
| If dose unit is Other, specify | UNKNOWN  |
| Frequency                      | once daily <input type="radio"/><br>twice daily <input type="radio"/><br>three times daily <input type="radio"/><br>four times daily <input type="radio"/><br>every other day <input type="radio"/><br>every week <input type="radio"/><br>every month <input type="radio"/><br>as needed <input type="radio"/><br>once <input checked="" type="radio"/><br>unknown <input type="radio"/><br>other <input type="radio"/> |
| If frequency is Other, specify |  |
| Route of administration        | Oral <input type="radio"/><br>Topical <input type="radio"/><br>Subcutaneous <input type="radio"/><br>Transdermal <input type="radio"/><br>Intraocular <input type="radio"/><br>Intramuscular <input checked="" type="radio"/>  |

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:08

|  |                          |                                     |
|--|--------------------------|-------------------------------------|
|  | 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)                           |                          | 27 APR 2021                         |
| Start date completely unknown                      |                          | False                               |
| Ongoing?   | Yes                      | <input type="checkbox"/>            |
|  | No                       | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy)             |                          | 27 APR 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"/>            |

US3092245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 02:38:58

Generated On: 09 Jun 2021 15:10:08

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3092245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

| Procedure/Surgery date (dd MMM<br>yyyy) | Procedure/Surgery    | Indication    | If indication is Other, specify |
|---|----------------------|---------------|---------------------------------|
| 22 NOV 2020                             | PHYSICAL THERAPY     | Adverse Event |                                 |
| 22 NOV 2020                             | OCCUPATIONAL THERAPY | Adverse Event |                                 |
| 03 MAR 2021                             | URODYNAMICS TESTING  | Adverse Event |                                 |
| 09 MAR 2021                             | CYTOSCOPY            | Adverse Event |                                 |

US3092245

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:10:08

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

US3092245

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:10:08

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 ☐

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

|  |  |
|--|--|
| SAEID  | USA-US086-2020-MRNA-1273-P301000007                              |
| 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                                      | VALENTINE  |
| Investigator's Last Name                                       | EBUH   |
| Site Address: Street   | 2701 S HAMPTON ROAD, SUITE 250                                   |
| Site Address: City   | DALLAS   |
| Site Address: State  | TX   |
| Site Address: Postal Code                                      | 75224  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)                             | 7  |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

|   |  |
|---|--|
| SAEID   | USA-US086-2020-MRNA-1273-P301000007                              |
| 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   | VALENTINE  |
| Investigator's Last Name  | EBUH   |
| Site Address: Street  | 2701 S HAMPTON ROAD, SUITE 250                                   |
| Site Address: City  | DALLAS   |
| Site Address: State   | TX   |
| Site Address: Postal Code   | 75224  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 7  |
| Date of submission (Pre-filled from custom function)  | 25/NOV/2020 11:03  |
| 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   |



US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

|   |  |
|---|--|
| SAEID   | USA-US086-2020-MRNA-1273-P301000007                              |
| 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   | VALENTINE  |
| Investigator's Last Name  | EBUH   |
| Site Address: Street  | 2701 S HAMPTON ROAD, SUITE 250                                   |
| Site Address: City  | DALLAS   |
| Site Address: State   | TX   |
| Site Address: Postal Code   | 75224  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 7  |
| Date of submission (Pre-filled from custom function)  | 21/DEC/2020 16:23  |
| 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   |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

|   |  |
|---|--|
| SAEID   | USA-US086-2020-MRNA-1273-P301000007                              |
| 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   | VALENTINE  |
| Investigator's Last Name  | EBUH   |
| Site Address: Street  | 2701 S HAMPTON ROAD, SUITE 250                                   |
| Site Address: City  | DALLAS   |
| Site Address: State   | TX   |
| Site Address: Postal Code   | 75224  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 7  |
| Date of submission (Pre-filled from custom function)  | 12/MAR/2021 11:59  |
| 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   |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

|   |  |
|---|--|
| SAEID   | USA-US086-2020-MRNA-1273-P301000007                              |
| 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   | VALENTINE  |
| Investigator's Last Name  | EBUH   |
| Site Address: Street  | 2701 S HAMPTON ROAD, SUITE 250                                   |
| Site Address: City  | DALLAS   |
| Site Address: State   | TX   |
| Site Address: Postal Code   | 75224  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 7  |
| Date of submission (Pre-filled from custom function)  | 12/MAR/2021 19:07  |
| 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   |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

|   |  |
|---|--|
| SAEID   | USA-US086-2020-MRNA-1273-P301000007                              |
| 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   | VALENTINE  |
| Investigator's Last Name  | EBUH   |
| Site Address: Street  | 2701 S HAMPTON ROAD, SUITE 250                                   |
| Site Address: City  | DALLAS   |
| Site Address: State   | TX   |
| Site Address: Postal Code   | 75224  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 7  |
| Date of submission (Pre-filled from custom function)  | 29/MAR/2021 10:20  |
| 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   |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

|   |  |
|---|--|
| SAEID   | USA-US086-2020-MRNA-1273-P301000007                              |
| 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   | VALENTINE  |
| Investigator's Last Name  | EBUH   |
| Site Address: Street  | 2701 S HAMPTON ROAD, SUITE 250                                   |
| Site Address: City  | DALLAS   |
| Site Address: State   | TX   |
| Site Address: Postal Code   | 75224  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 7  |
| Date of submission (Pre-filled from custom function)  | 02/APR/2021 05:56  |
| 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   |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

|   |  |
|---|--|
| SAEID   | USA-US086-2020-MRNA-1273-P301000007                              |
| 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   | VALENTINE  |
| Investigator's Last Name  | EBUH   |
| Site Address: Street  | 2701 S HAMPTON ROAD, SUITE 250                                   |
| Site Address: City  | DALLAS   |
| Site Address: State   | TX   |
| Site Address: Postal Code   | 75224  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 7  |
| Date of submission (Pre-filled from custom function)  | 12/APR/2021 11:43  |
| 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   |

US3092245

Folder: SAE USA-US086-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

|  |  |
|--|--|
| SAEID  | USA-US086-2021-MRNA-1273-P301000014                              |
| 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                                      | VALENTINE  |
| Investigator's Last Name                                       | EBUH   |
| Site Address: Street   | 2701 S HAMPTON ROAD, SUITE 250                                   |
| Site Address: City   | DALLAS   |
| Site Address: State  | TX   |
| Site Address: Postal Code                                      | 75224  |
| Investigator Country   | US   |
| E2B Transmit Flag (Derived/Hidden)                             | 1  |

US3092245

Folder: SAE USA-US086-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 02:23:41

Generated On: 09 Jun 2021 15:10:08

|   |  |
|---|--|
| SAEID   | USA-US086-2021-MRNA-1273-P301000014                              |
| 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   | VALENTINE  |
| Investigator's Last Name  | EBUH   |
| Site Address: Street  | 2701 S HAMPTON ROAD, SUITE 250                                   |
| Site Address: City  | DALLAS   |
| Site Address: State   | TX   |
| Site Address: Postal Code   | 75224  |
| Investigator Country  | US   |
| E2B Transmit Flag (Derived/Hidden)  | 1  |
| Date of submission (Pre-filled from custom function)  | 02/APR/2021 12:05  |
| 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

US3092245 (Prod: Global Medical Research - M3 Wake Research)

**US3092245**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:10:08**

[Participant ID](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)                      | 23 Feb 2021 03:47:23 |
| User entered 'US3092245'  | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 27 Aug 2020 18:34:25 |

**US3092245**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Was this visit performed?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:52:33 |

**US3092245**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                      | 23 Feb 2021 03:47:23 |
| User entered '27 AUG 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 27 Aug 2020 18:34:26 |

**US3092245**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                   | Time (GMT)           |
|--------------------------------|------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)       | 26 Apr 2021 08:52:46 |
| User signature succeeded.      | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered 'Clinic (Clinic)' | Shraddha Dubal (b) (4) | 27 Aug 2020 18:52:33 |

**US3092245**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Folder OID](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered 'SCRN' | System           | 27 Aug 2020 18:52:33 |

US3092245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:08

Date of Birth (MMM yyyy)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 26 Apr 2021 08:52:46 |
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User closed query 'Per CDM: Please record the data for all the relevant forms. Thank you.' (Site from DM).          | (b) (4)<br>(b) (4), (b) (6)         | 09 Nov 2020 22:02:58 |
| Query 'Per CDM: Please record the data for all the relevant forms. Thank you.' answered with 'DONE' (Site from DM). | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:40:15 |
| User opened query 'Per CDM: Please record the data for all the relevant forms. Thank you.' (Site from DM).          | (b) (4), (b) (6)                    | 05 Nov 2020 10:06:07 |
| User entered (b) (6) 1954'  | RWS_ENDPOINT<br>ENDPOINT (b) (4)    | 27 Aug 2020 18:34:27 |

**US3092245**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:10:08**

[Age](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '66'         | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:11 |



**US3092245**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:10:08**

[Age Units](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered 'YEARS' | System           | 27 Aug 2020 18:53:11 |

**US3092245**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:10:08**

[Age \(Derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered '66' | System           | 27 Aug 2020 18:53:44 |

US3092245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:08

Sex

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)            | 26 Apr 2021 08:52:46 |
| User signature succeeded.   | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User closed query 'Per CDM: Sex is recoded as 'Female'. However childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. Thank you.' (Site from DM).          | (b) (4)<br>(b) (4), (b) (6) | 09 Nov 2020 22:03:10 |
| Query 'Per CDM: Sex is recoded as 'Female'. However childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. Thank you.' answered with 'DONE' (Site from DM). | Marissa Cervenka (b) (4)    | 06 Nov 2020 00:40:17 |
| User opened query 'Per CDM: Sex is recoded as 'Female'. However childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. Thank you.' (Site from DM).          | (b) (4), (b) (6)            | 05 Nov 2020 10:04:15 |
| User closed query 'Data is required. Please complete.' (Site from System).  | System                      | 27 Aug 2020 18:53:21 |
| Query 'Data is required. Please complete.' answered by data change (Site from System).  | System                      | 27 Aug 2020 18:53:21 |
| User entered 'Female (F)' reason for change: Data Entry Error   | Shraddha Dubal (b) (4)      | 27 Aug 2020 18:53:21 |
| User opened query 'Data is required. Please complete.' (Site from System).  | System                      | 27 Aug 2020 18:53:11 |
| User entered empty.   | Shraddha Dubal (b) (4)      | 27 Aug 2020 18:53:11 |

**US3092245**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:10:08**

[Ethnicity](#)

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded.                                      | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:11 |

**US3092245**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:10:08**

[White](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:11 |

**US3092245**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:10:08**

[Black](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'I'          | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:11 |

**US3092245**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:10:08**

[Asian](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:11 |

**US3092245**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:10:08**

[American Indian or Alaska Native](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:11 |



**US3092245**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:10:08**

[Native Hawaiian or other Pacific Islander](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered '0'          | Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:11 |

**US3092245**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:10:08**

[Other](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:11 |

US3092245

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:10:08

If race is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:11 |

**US3092245**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:10:08**

[Unknown](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:11 |

**US3092245**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:10:08**

[Not reported](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:11 |

US3092245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:08

Date of Informed Consent (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered '27 Aug 2020' | Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:44 |

**US3092245**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:10:08**

[Month and Year of Informed Consent \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered 'Aug 2020' | System           | 27 Aug 2020 18:53:44 |

**US3092245**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:10:08**

[Year of Informed Consent \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered '2020' | System           | 27 Aug 2020 18:53:44 |



US3092245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:08

[Protocol Version](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)                | 27 Aug 2020 18:54:28 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 27 Aug 2020 18:54:28 |
| User entered 'Amendment 3 (3)' reason for change: Data Entry Error                     | Shraddha Dubal (b) (4) | 27 Aug 2020 18:54:28 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                | 27 Aug 2020 18:53:44 |
| User entered empty.  | System                 | 27 Aug 2020 18:53:44 |
|  | Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:44 |
|  | (b) (4)                |                      |

US3092245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:08

[Was participant enrolled in the study?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:44 |

**US3092245**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:10:08**

[If No, indicate reason for screen fail](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:44 |

US3092245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:08

If reason for screen fail is Other, specify

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:44 |

**US3092245**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:10:08**

[Was this participant screened previously?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | Shraddha Dubal (b) (4) | 27 Aug 2020 18:53:44 |

**US3092245**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:10:08**

[If Yes, previous participant number](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 27 Aug 2020 18:34:26 |

US3092245

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:10:08

[Enrollment Trigger](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered 'I'  | System           | 27 Aug 2020 18:54:43 |

US3092245

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:10:08

[Did the participant meet all eligibility criteria?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:54:43 |



US3092245

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:10:08

[Were any significant conditions reported?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 05 Nov 2020 23:37:40 |

US3092245

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:10:08

Condition

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 30 Apr 2021 07:31:18 |
| Data hard unlocked.   |                                     | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                                     | 26 Apr 2021 08:52:46 |
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)     | 05 Nov 2020 23:39:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)                | 05 Nov 2020 23:39:25 |
| Data point term sent to Coder   | System                              | 05 Nov 2020 23:38:45 |
| User entered 'BILATERAL KNEE PAIN'  | Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:38:25 |

**US3092245**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.        |  | 29 Apr 2021 09:25:32 |
| Data hard locked.          |  | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'UN UNK 2015' | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:38:25 |

US3092245

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:10:08

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:38:25 |

**US3092245**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:38:25 |

**US3092245**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:10:08**

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:38:25 |

**US3092245**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:38:25 |

**US3092245**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2015' | System           | 05 Nov 2020 23:38:25 |



**US3092245**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2015' | System           | 05 Nov 2020 23:38:25 |

**US3092245**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:38:25 |

**US3092245**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:38:25 |

US3092245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:08

[Condition](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 30 Apr 2021 07:31:18 |
| Data hard unlocked.   |                                     | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                                     | 26 Apr 2021 08:52:46 |
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Subtotal hysterectomy - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)     | 05 Nov 2020 23:40:24 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)                | 05 Nov 2020 23:40:24 |
| Data point term sent to Coder   | System                              | 05 Nov 2020 23:39:45 |
| User entered 'PARTIAL HYSTERECTOMY'   | Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:38:54 |

**US3092245**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.        |  | 29 Apr 2021 09:25:32 |
| Data hard locked.          |  | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'UN UNK 2001' | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:38:54 |

**US3092245**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:38:54 |

US3092245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:08

[Condition ongoing at study entry](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 30 Apr 2021 07:31:18 |
| Data hard unlocked.   |                                     | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                                     | 26 Apr 2021 08:52:46 |
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User closed query 'Per CDM: Please note that it is unusual for a procedure/surgery to be ongoing and these usually have the same start and end date. Kindly review and update as appropriate. ' (Site from DM).             | (b) (4)<br>(b) (4), (b) (6)         | 11 Dec 2020 11:41:26 |
| Query 'Per CDM: Please note that it is unusual for a procedure/surgery to be ongoing and these usually have the same start and end date. Kindly review and update as appropriate. ' answered with 'Updated' (Site from DM). | Catina Adams (b) (4)<br>(b) (4)     | 10 Dec 2020 22:04:16 |
| User entered 'No (N)' reason for change: Data Entry Error   | Catina Adams (b) (4)<br>(b) (4)     | 10 Dec 2020 22:03:34 |
| User opened query 'Per CDM: Please note that it is unusual for a procedure/surgery to be ongoing and these usually have the same start and end date. Kindly review and update as appropriate. ' (Site from DM).             | (b) (4), (b) (6)                    | 13 Nov 2020 08:05:30 |
| User entered 'Yes (Y)'  | Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:38:54 |

US3092245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:08

If No, please specify the stop date (dd MMM yyyy)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.                             | (b) (4), (b) (6)         | 30 Apr 2021 07:31:18 |
| Data hard unlocked.                           |                          | 29 Apr 2021 09:25:32 |
| Data hard locked.                             |                          | 26 Apr 2021 08:52:46 |
| User signature succeeded.                     | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'UN UNK 2001' reason for change: | (b) (4)                  |                      |
| Data Entry Error                              | Catina Adams (b) (4)     | 10 Dec 2020 22:03:34 |
| User entered empty.                           | (b) (4)                  |                      |
|   | Marissa Cervenka (b) (4) | 05 Nov 2020 23:38:54 |
|   | (b) (4)                  |                      |



US3092245

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:10:08

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:38:54 |

**US3092245**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2001' | System           | 05 Nov 2020 23:38:54 |

**US3092245**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2001' | System           | 05 Nov 2020 23:38:54 |

**US3092245**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2001' | System           | 10 Dec 2020 22:03:34 |
| User entered empty.     | System           | 05 Nov 2020 23:38:54 |

**US3092245**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2001' | System           | 10 Dec 2020 22:03:34 |
| User entered empty. | System           | 05 Nov 2020 23:38:54 |

US3092245

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:10:08

[Condition](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 30 Apr 2021 07:31:18 |
| Data hard unlocked.   |                                     | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                                     | 26 Apr 2021 08:52:46 |
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)     | 05 Nov 2020 23:41:26 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)     | 05 Nov 2020 23:41:26 |
| Data point term sent to Coder   | System                              | 05 Nov 2020 23:40:47 |
| User entered 'POST MENOPAUSAL'  | Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:40:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.        |  | 29 Apr 2021 09:25:32 |
| Data hard locked.          |  | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'UN UNK 2001' | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:40:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:40:38 |



US3092245

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:10:08

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:40:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:10:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:40:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:40:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2001' | System           | 05 Nov 2020 23:40:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2001' | System           | 05 Nov 2020 23:40:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:40:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:40:38 |

US3092245

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:10:08

[Condition](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 30 Apr 2021 07:31:18 |
| Data hard unlocked.  |                                     | 29 Apr 2021 09:25:32 |
| Data hard locked.  |                                     | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)     | 05 Nov 2020 23:43:28 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)                | 05 Nov 2020 23:43:28 |
| Data point term sent to Coder  | System                              | 05 Nov 2020 23:42:50 |
| User entered 'HYPERTENSION'  | Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:41:58 |



**US3092245**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.        |  | 29 Apr 2021 09:25:32 |
| Data hard locked.          |  | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'UN UNK 2015' | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:41:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:41:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:41:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:10:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:41:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:41:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2015' | System           | 05 Nov 2020 23:41:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2015' | System           | 05 Nov 2020 23:41:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:41:58 |



**US3092245**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:41:58 |

US3092245

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:10:08

Condition

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 30 Apr 2021 07:31:18 |
| Data hard unlocked.   |                                     | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                                     | 26 Apr 2021 08:52:46 |
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)     | 05 Nov 2020 23:58:30 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)                | 05 Nov 2020 23:58:30 |
| Data point term sent to Coder   | System                              | 05 Nov 2020 23:42:50 |
| User entered 'SHINGLES'   | Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:42:33 |

**US3092245**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.        |  | 29 Apr 2021 09:25:32 |
| Data hard locked.          |  | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'UN UNK 2017' | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:42:33 |

US3092245

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:10:08

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:42:33 |

**US3092245**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:42:33 |

**US3092245**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:10:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.        |  | 29 Apr 2021 09:25:32 |
| Data hard locked.          |  | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'UN UNK 2017' | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:42:33 |

US3092245

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:10:08

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:42:33 |

**US3092245**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2017' | System           | 05 Nov 2020 23:42:33 |



**US3092245**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2017' | System           | 05 Nov 2020 23:42:33 |

**US3092245**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2017' | System           | 05 Nov 2020 23:42:33 |

**US3092245**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2017' | System           | 05 Nov 2020 23:42:33 |

US3092245

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:10:08

[Condition](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 30 Apr 2021 07:31:18 |
| Data hard unlocked.   |                                     | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                                     | 26 Apr 2021 08:52:46 |
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Flank pain, LLT: Flank pain - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)     | 11 Nov 2020 08:38:46 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.   | Coder Import (b) (4)                | 11 Nov 2020 08:38:46 |
| Data point term sent to Coder   | System                              | 05 Nov 2020 23:43:51 |
| User entered 'UPPER LEFT TORSO PAIN SECONDARY TO SHINGLES'  | Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:43:19 |

**US3092245**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.        |  | 29 Apr 2021 09:25:32 |
| Data hard locked.          |  | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'UN UNK 2017' | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:43:19 |

US3092245

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:10:08

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:43:19 |

**US3092245**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:43:19 |

**US3092245**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:10:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:43:19 |



US3092245

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:10:08

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:43:19 |

**US3092245**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2017' | System           | 05 Nov 2020 23:43:19 |

**US3092245**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2017' | System           | 05 Nov 2020 23:43:19 |

**US3092245**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:43:19 |

**US3092245**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:43:19 |

US3092245

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:10:08

Condition

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 30 Apr 2021 07:31:18 |
| Data hard unlocked.   |                                     | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                                     | 26 Apr 2021 08:52:46 |
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)     | 05 Nov 2020 23:44:27 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)                | 05 Nov 2020 23:44:27 |
| Data point term sent to Coder   | System                              | 05 Nov 2020 23:43:51 |
| User entered 'DEPRESSION'   | Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:43:45 |

**US3092245**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.        |  | 29 Apr 2021 09:25:32 |
| Data hard locked.          |  | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'UN UNK 2017' | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:43:45 |

US3092245

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:10:08

Start date completely unknown

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:43:45 |



**US3092245**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:43:45 |

**US3092245**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:10:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:43:45 |

**US3092245**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:43:45 |

**US3092245**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2017' | System           | 05 Nov 2020 23:43:45 |

**US3092245**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2017' | System           | 05 Nov 2020 23:43:45 |

**US3092245**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:43:45 |

**US3092245**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:43:45 |

US3092245

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:10:08

[Condition](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 30 Apr 2021 07:31:18 |
| Data hard unlocked.  |                                     | 29 Apr 2021 09:25:32 |
| Data hard locked.  |                                     | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma both eyes - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)     | 05 Nov 2020 23:45:25 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4)     | 05 Nov 2020 23:45:25 |
| Data point term sent to Coder  | System                              | 05 Nov 2020 23:44:51 |
| User entered 'BILATERAL GLAUCOMA'  | Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:44:28 |



**US3092245**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.        |  | 29 Apr 2021 09:25:32 |
| Data hard locked.          |  | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'UN UNK 2017' | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:44:28 |

**US3092245**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:44:28 |

**US3092245**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:44:28 |

**US3092245**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:10:08**

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:44:28 |

**US3092245**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:44:28 |

**US3092245**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2017' | System           | 05 Nov 2020 23:44:28 |

**US3092245**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2017' | System           | 05 Nov 2020 23:44:28 |

**US3092245**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:44:28 |



**US3092245**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:44:28 |

US3092245

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:10:08

Condition

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                           | 30 Apr 2021 07:31:18 |
| Data hard unlocked.   | (b) (4), (b) (6)                           | 29 Apr 2021 09:25:32 |
| User signature succeeded.   | Valentine Ebuh (b) (4)                     | 29 Apr 2021 02:23:41 |
| Data hard locked.   | (b) (4)<br>(b) (4), (b) (6)                | 26 Apr 2021 08:52:46 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.             | Coder Import (b) (4)<br>(b) (4)            | 20 Apr 2021 19:17:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)            | 20 Apr 2021 19:17:41 |
| Data point term sent to Coder   | System                                     | 20 Apr 2021 19:16:49 |
| Coding entries removed.   | (b) (4), (b) (6)                           | 20 Apr 2021 19:16:11 |
| Signature has been broken.  | (b) (4), (b) (6)                           | 20 Apr 2021 19:16:11 |
| User entered 'HYPERLIPIDEMIA' reason for change: Data Entry Error   | (b) (4), (b) (6)                           | 20 Apr 2021 19:16:11 |
| User signature succeeded.   | Valentine Ebuh (b) (4)                     | 23 Feb 2021 03:47:23 |
| User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 05 Nov 2020 23:46:28 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4)            | 05 Nov 2020 23:46:28 |
| Data point term sent to Coder   | System                                     | 05 Nov 2020 23:45:52 |
| User entered 'HYPERCHOLESTEROLEMIA'   | Marissa Cervenka (b) (4)<br>(b) (4)        | 05 Nov 2020 23:45:02 |

**US3092245**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.        |  | 29 Apr 2021 09:25:32 |
| Data hard locked.          |  | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'UN UNK 2017' | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:45:02 |

**US3092245**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:45:02 |

**US3092245**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:45:02 |

US3092245

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:10:08

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:45:02 |

**US3092245**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:45:02 |

**US3092245**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2017' | System           | 05 Nov 2020 23:45:02 |



**US3092245**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2017' | System           | 05 Nov 2020 23:45:02 |

**US3092245**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:45:02 |

**US3092245**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:45:02 |

US3092245

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:10:08

[Condition](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 30 Apr 2021 07:31:18 |
| Data hard unlocked.  |                                     | 29 Apr 2021 09:25:32 |
| Data hard locked.  |                                     | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain ankle - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4)     | 05 Nov 2020 23:46:29 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)                | 05 Nov 2020 23:46:29 |
| Data point term sent to Coder  | System                              | 05 Nov 2020 23:45:52 |
| User entered 'BILATERAL ANKLE PAIN'  | Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:45:32 |

**US3092245**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.        |  | 29 Apr 2021 09:25:32 |
| Data hard locked.          |  | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'UN UNK 2015' | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:45:32 |

**US3092245**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:45:32 |

**US3092245**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:10:08**

[Condition ongoing at study entry](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:45:32 |

**US3092245**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:10:08**

If No, please specify the stop date (dd MMM yyyy)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:45:32 |



**US3092245**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop date completely unknown](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:45:32 |

**US3092245**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2015' | System           | 05 Nov 2020 23:45:32 |

**US3092245**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2015' | System           | 05 Nov 2020 23:45:32 |

**US3092245**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:45:32 |

**US3092245**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 05 Nov 2020 23:45:32 |

US3092245

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:10:08

Condition

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 30 Apr 2021 07:31:18 |
| Data hard unlocked.   |                                 | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                                 | 26 Apr 2021 08:52:46 |
| User signature succeeded.   | Valentine Ebuh (b) (4)          | 23 Mar 2021 22:52:09 |
| User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0. | (b) (4)<br>Coder Import (b) (4) | 08 Mar 2021 16:09:39 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)            | 08 Mar 2021 16:09:39 |
| Data point term sent to Coder   | System                          | 08 Mar 2021 16:08:54 |
| User entered 'Overactive Bladder'   | Catina Adams (b) (4)<br>(b) (4) | 08 Mar 2021 16:07:58 |

US3092245

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:10:08

Start date (dd MMM yyyy)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                           | 30 Apr 2021 07:31:18 |
| Data hard unlocked.  |  | 29 Apr 2021 09:25:32 |
| User signature succeeded.                                      | Valentine Ebuh (b) (4)                     | 29 Apr 2021 02:23:41 |
| Data hard locked.  | (b) (4)<br>(b) (4), (b) (6)                | 26 Apr 2021 08:52:46 |
| Signature has been broken.                                     |  | 20 Apr 2021 19:16:40 |
| User entered 'UN Jun 2020' reason for change: Data Entry Error |  | 20 Apr 2021 19:16:40 |
| User signature succeeded.                                      | Valentine Ebuh (b) (4)                     | 23 Mar 2021 22:52:09 |
| User entered '20 Jun 2020'                                     | (b) (4)<br>Catina Adams (b) (4)<br>(b) (4) | 08 Mar 2021 16:07:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                     | 23 Mar 2021 22:52:09 |
| User entered '0'          | (b) (4)<br>Catina Adams (b) (4)<br>(b) (4) | 08 Mar 2021 16:07:58 |



**US3092245**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:10:08**

[Condition ongoing at study entry](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                     | 23 Mar 2021 22:52:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>Catina Adams (b) (4)<br>(b) (4) | 08 Mar 2021 16:07:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:10:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                     | 23 Mar 2021 22:52:09 |
| User entered empty.       | (b) (4)<br>Catina Adams (b) (4)<br>(b) (4) | 08 Mar 2021 16:07:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop date completely unknown](#)

| Audit                     | User                                       | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                           | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |  | 29 Apr 2021 09:25:32 |
| Data hard locked.         |  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                     | 23 Mar 2021 22:52:09 |
| User entered '0'          | (b) (4)<br>Catina Adams (b) (4)<br>(b) (4) | 08 Mar 2021 16:07:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jun 2020' | System           | 08 Mar 2021 16:07:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2020' | System           | 08 Mar 2021 16:07:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 08 Mar 2021 16:07:58 |

**US3092245**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 08 Mar 2021 16:07:58 |

US3092245

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:10:08

[Condition](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 30 Apr 2021 07:31:18 |
| Data hard unlocked.  |                                 | 29 Apr 2021 09:25:32 |
| User signature succeeded.  | Valentine Ebuh (b) (4)          | 29 Apr 2021 02:23:41 |
| Data hard locked.  | (b) (4)<br>(b) (4), (b) (6)     | 26 Apr 2021 08:52:46 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 20 Apr 2021 19:18:29 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)<br>(b) (4) | 20 Apr 2021 19:18:29 |
| Data point term sent to Coder  | System                          | 20 Apr 2021 19:17:51 |
| User entered 'MUSCLE SPASMS BILATERAL LEGS'  | (b) (4), (b) (6)                | 20 Apr 2021 19:17:38 |



**US3092245**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 07:31:18 |
| Data hard unlocked.        |                             | 29 Apr 2021 09:25:32 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| Data hard locked.          | (b) (4)<br>(b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered 'UN UNK 2017' |                             | 20 Apr 2021 19:17:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |                             | 29 Apr 2021 09:25:32 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| Data hard locked.         | (b) (4)<br>(b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered '0'          |                             | 20 Apr 2021 19:17:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |                             | 29 Apr 2021 09:25:32 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| Data hard locked.         | (b) (4)<br>(b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered 'Yes (Y)'    |                             | 20 Apr 2021 19:17:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:10:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |                             | 29 Apr 2021 09:25:32 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| Data hard locked.         | (b) (4)<br>(b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered empty.       |                             | 20 Apr 2021 19:17:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |                             | 29 Apr 2021 09:25:32 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| Data hard locked.         | (b) (4)<br>(b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered '0'          |                             | 20 Apr 2021 19:17:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2017' | System           | 20 Apr 2021 19:17:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2017' | System           | 20 Apr 2021 19:17:38 |

**US3092245**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 20 Apr 2021 19:17:38 |



**US3092245**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 20 Apr 2021 19:17:38 |

US3092245

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:10:08

Condition

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                | 30 Apr 2021 07:31:18 |
| Data hard unlocked.   |                                 | 29 Apr 2021 09:25:32 |
| User signature succeeded.   | Valentine Ebuh (b) (4)          | 29 Apr 2021 02:23:41 |
| Data hard locked.   | (b) (4)<br>(b) (4), (b) (6)     | 26 Apr 2021 08:52:46 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 20 Apr 2021 19:19:33 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 20 Apr 2021 19:19:33 |
| Data point term sent to Coder   | System                          | 20 Apr 2021 19:18:52 |
| User entered 'INTERMITTENT SHORTNESS OF BREATH'   | (b) (4), (b) (6)                | 20 Apr 2021 19:18:20 |

**US3092245**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 30 Apr 2021 07:31:18 |
| Data hard unlocked.        |                             | 29 Apr 2021 09:25:32 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| Data hard locked.          | (b) (4)<br>(b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered 'UN UNK 2010' |                             | 20 Apr 2021 19:18:20 |

**US3092245**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |                             | 29 Apr 2021 09:25:32 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| Data hard locked.         | (b) (4)<br>(b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered '0'          |                             | 20 Apr 2021 19:18:20 |

**US3092245**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Condition ongoing at study entry](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |                             | 29 Apr 2021 09:25:32 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| Data hard locked.         | (b) (4)<br>(b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered 'Yes (Y)'    |                             | 20 Apr 2021 19:18:20 |

**US3092245**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:10:08**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |                             | 29 Apr 2021 09:25:32 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| Data hard locked.         | (b) (4)<br>(b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered empty.       |                             | 20 Apr 2021 19:18:20 |

**US3092245**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 30 Apr 2021 07:31:18 |
| Data hard unlocked.       |                             | 29 Apr 2021 09:25:32 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| Data hard locked.         | (b) (4)<br>(b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered '0'          |                             | 20 Apr 2021 19:18:20 |

**US3092245**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Month and Year \(derived\)](#)

| Audit                   | User             | Time (GMT)           |
|-------------------------|------------------|----------------------|
| Data hard locked.       | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked.     |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.       |                  | 26 Apr 2021 08:52:46 |
| User entered 'Jan 2010' | System           | 20 Apr 2021 19:18:20 |



**US3092245**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Start Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered '2010' | System           | 20 Apr 2021 19:18:20 |

**US3092245**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Month and Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 20 Apr 2021 19:18:20 |

**US3092245**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Stop Year \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 30 Apr 2021 07:31:18 |
| Data hard unlocked. |                  | 29 Apr 2021 09:25:32 |
| Data hard locked.   |                  | 26 Apr 2021 08:52:46 |
| User entered empty. | System           | 20 Apr 2021 19:18:20 |

US3092245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

[Were vital signs assessed?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 05 Nov 2020 23:47:59 |

US3092245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '27 Aug 2020' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:47:59 |

**US3092245**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

**Time of assessment (00:00-23:59)**

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '12:50'      | Marissa Cervenka (b) (4) | 05 Nov 2020 23:47:59 |

**US3092245**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered '27 Aug 2020 12:50' | System           | 05 Nov 2020 23:47:59 |

US3092245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

Height (xxx.x)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '152.4' cm   | (b) (4)                  |                      |
|                           | Marissa Cervenka (b) (4) | 05 Nov 2020 23:47:59 |
| DataPoint set to visible. | (b) (4)                  |                      |
|                           | System                   | 27 Aug 2020 18:54:43 |



US3092245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

Weight (xxx.x)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered '165.1' kg   | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:47:59 |
| DataPoint set to visible. | (b) (4)<br>System                   | 27 Aug 2020 18:54:43 |

US3092245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

BMI (xxx.x)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered '71.08486'   | System           | 05 Nov 2020 23:47:59 |
| DataPoint set to visible. | System           | 27 Aug 2020 18:54:43 |

**US3092245**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[BMI units](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered 'kg/m2'      | System           | 05 Nov 2020 23:47:59 |
| DataPoint set to visible. | System           | 27 Aug 2020 18:54:43 |

US3092245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

Temperature (xxx.x)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded.                | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered missing code ND - Not Done. | Marissa Cervenka (b) (4) | 05 Nov 2020 23:47:59 |

US3092245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

[Route of measurement](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered empty.       | Marissa Cervenka (b) (4) | 05 Nov 2020 23:47:59 |

**US3092245**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[If Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:47:59 |

**US3092245**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse \(xxx\)](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded.                | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered missing code ND - Not Done. | Marissa Cervenka (b) (4) | 05 Nov 2020 23:47:59 |

**US3092245**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered 'bpm' | System           | 05 Nov 2020 23:47:59 |



US3092245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate \(xxx\)](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded.                | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered missing code ND - Not Done. | Marissa Cervenka (b) (4) | 05 Nov 2020 23:47:59 |

US3092245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered 'breaths/min' | System           | 05 Nov 2020 23:47:59 |

US3092245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

Systolic Blood Pressure (xxx)

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 26 Apr 2021 08:52:46 |
| User signature succeeded.                | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered missing code ND - Not Done. | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:47:59 |

US3092245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered 'mmHg' | System           | 05 Nov 2020 23:47:59 |

US3092245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

Diastolic Blood Pressure (xxx)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded.                | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered missing code ND - Not Done. | Marissa Cervenka (b) (4) | 05 Nov 2020 23:47:59 |

**US3092245**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
| User entered 'mmHg' | System           | 05 Nov 2020 23:47:59 |

US3092245

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
|                   |                  |                      |

**US3092245**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Weight \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 26 Apr 2021 08:52:46 |
|                   |                  |                      |



**US3092245**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:10:08**

[Was the physical examination performed?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 05 Nov 2020 23:48:15 |

**US3092245**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:10:08**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '27 Aug 2020' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:48:15 |

US3092245

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:10:08

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '27 Aug 2020' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:49:39 |

US3092245

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:10:08

[Is the participant of childbearing potential?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 05 Nov 2020 23:49:39 |

US3092245

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:10:08

If No, what is the reason?

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded.   | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System). | (b) (4)                  | 05 Nov 2020 23:50:06 |
| User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System). | System                   | 05 Nov 2020 23:49:39 |
| User entered 'Surgically sterile (SURGICALLY STERILE)'  | Marissa Cervenka (b) (4) | 05 Nov 2020 23:49:39 |

**US3092245**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:10:08**

[If Partner medically sterile or Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered empty.       | Marissa Cervenka (b) (4) | 05 Nov 2020 23:49:39 |

US3092245

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:10:08

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

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'UN UNK 2001' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:49:39 |

**US3092245**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:10:08**

[Date of surgery unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '0'          | Marissa Cervenka (b) (4) | 05 Nov 2020 23:49:39 |



**US3092245**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:10:08**

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

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded.                              | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered empty; reason for change Data Entry Error | (b) (4)                  |                      |
|  | Marissa Cervenka (b) (4) | 05 Nov 2020 23:50:06 |
| User entered 'UN UNK 2001'                             | (b) (4)                  |                      |
|  | Marissa Cervenka (b) (4) | 05 Nov 2020 23:49:39 |
|  | (b) (4)                  |                      |

**US3092245**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:10:08**

[Date of last menstruation unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '0'          | Marissa Cervenka (b) (4) | 05 Nov 2020 23:49:39 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                             | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)                       | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>Shraddha Dubal (b) (4)<br>(b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

**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)       | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

**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)       | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

[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)       | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |



US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

**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)       | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

**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)       | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

[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)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

**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)       | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

**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)       | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

**US3092245**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:10:08**

**Other**

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

[Specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered empty.       | Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

No Risk Identified

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |



US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

**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)       | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered '0'          | Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

**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)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

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)       | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered '0'          | Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

[Resides in a single family home](#) (i.e., detached housing)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'I'          | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

**US3092245**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:10:08**

**Other**

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:10:08

[Specify](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 26 Apr 2021 08:52:46 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:06 |

US3092245

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:10:08

[Was this visit performed?](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:48 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27AUG2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).          | (b) (4)<br>(b) (4), (b) (6)         | 09 Nov 2020 14:07:39 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27AUG2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'DONE' (Site from DM). | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:41:13 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27AUG2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).          | (b) (4), (b) (6)                    | 21 Oct 2020 10:42:15 |
| User entered 'Yes (Y)'   | Shraddha Dubal (b) (4)<br>(b) (4)   | 27 Aug 2020 18:55:23 |



US3092245

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:10:08

Visit date (dd MMM yyyy)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:48 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 27-AUG-2020 is reported under Visit 1 Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM).          | (b) (4)<br>(b) (4), (b) (6)         | 18 Nov 2020 12:29:52 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample dated 27-AUG-2020 is reported under Visit 1 Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' answered with 'DONE' (Site from DM). | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:41:18 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 27-AUG-2020 is reported under Visit 1 Day 1 in PPD Central lab; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify.' (Site from DM).          | (b) (4), (b) (6)                    | 29 Oct 2020 12:59:42 |
| User entered '27 Aug 2020'  | Shraddha Dubal (b) (4)<br>(b) (4)   | 27 Aug 2020 18:55:23 |

US3092245

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:10:08

[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 23:19:38 |
| User signature succeeded.      | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:48 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:55:23 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'VISIT1' | System           | 27 Aug 2020 18:55:23 |

US3092245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:08

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

| Audit                      | User  | Time (GMT)           |
|----------------------------|---|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                            | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                      | 23 Feb 2021 03:47:23 |
| User entered '27 AUG 2020' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 27 Aug 2020 18:49:19 |

US3092245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:08

[What was the participant's randomization number?](#)

| Audit                     | User  | Time (GMT)           |
|---------------------------|---|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                            | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                      | 23 Feb 2021 03:47:23 |
| User entered '188546'     | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 27 Aug 2020 18:49:19 |

US3092245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:08

[In what Cohort was the participant enrolled?](#)

| Audit                         | User  | Time (GMT)           |
|-------------------------------|---|----------------------|
| Data hard locked.             | (b) (4), (b) (6)                            | 03 Apr 2021 23:19:38 |
| User signature succeeded.     | Valentine Ebuh (b) (4)                      | 23 Feb 2021 03:47:23 |
| User entered '>=65 years (3)' | (b) (4)<br>RWS_ENDPOINT<br>ENDPOINT (b) (4) | 27 Aug 2020 18:49:19 |

US3092245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:08

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 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                       | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>Shraddha Dubal (b) (4)<br>(b) (4) | 27 Aug 2020 18:56:57 |

US3092245

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:10:08

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 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                       | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>Shraddha Dubal (b) (4)<br>(b) (4) | 27 Aug 2020 18:56:57 |



**US3092245**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:10:08**

**Severe obesity (body mass index > or = 40kg/m2**

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:56:57 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:10:08**

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:56:57 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:10:08**

[Liver Disease](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:56:57 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:10:08**

[Human Immunodeficiency Virus \(HIV\) infection](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                            | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded.                    | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'                        | Marissa Cervenka (b) (4) | 05 Nov 2020 23:45:51 |
| Amendment Manager: DataPoint set to visible. | System                   | 19 Sep 2020 08:18:41 |
| Amendment Manager inserted this DataPoint.   | System                   | 19 Sep 2020 08:18:40 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:08

Height

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded.                | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:48 |
| User entered missing code ND - Not Done. | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:08

Weight

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded.                | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered missing code ND - Not Done. | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:08

Height

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded.                | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:48 |
| User entered missing code ND - Not Done. | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:08

Weight

| Audit                                    | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded.                | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:48 |
| User entered missing code ND - Not Done. | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |



US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Timepoint](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |
|  | (b) (4)                  |                      |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Were vital signs assessed?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:48 |
| User entered '27 Aug 2020' | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

**Time of assessment (00:00-23:59)**

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered '12:50'      | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered '27 Aug 2020 12:50' | System           | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Temperature (xxx.x)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered '98.2' F     | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Route of measurement](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered 'Oral (Oral)' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[If Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered empty.       | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |



US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Pulse \(xxx\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered '77'         | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'bpm' | System           | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:48 |
| User entered '18'         | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'breaths/min' | System           | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Systolic Blood Pressure (xxx)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered '164'        | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'mmHg' | System           | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Diastolic Blood Pressure (xxx)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered '76'         | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'mmHg' | System           | 05 Nov 2020 23:54:18 |



US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:08

Height

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded.                | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered missing code ND - Not Done. | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:10:08**

[Weight](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                        | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded.                | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered missing code ND - Not Done. | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Timepoint](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Were vital signs assessed?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered '27 Aug 2020' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Time of assessment (00:00-23:59)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:48 |
| User entered '14:24'      | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered '27 Aug 2020 14:24' | System           | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Temperature (xxx.x)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered '97.3' F     | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |



US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Route of measurement](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered 'Oral (Oral)' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[If Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:48 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse \(xxx\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered '76'         | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'bpm' | System           | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:48 |
| User entered '18'         | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'breaths/min' | System           | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Systolic Blood Pressure (xxx)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered '138'        | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'mmHg' | System           | 05 Nov 2020 23:54:18 |



US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Diastolic Blood Pressure (xxx)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:48 |
| User entered '82'         | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'mmHg' | System           | 05 Nov 2020 23:54:18 |

US3092245

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:08

[Was the physical examination performed?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:24 |

US3092245

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:08

Date of examination (*dd MMM yyyy*)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:54:24 |

US3092245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[Was study treatment given?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:57:14 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[If No, reason not given](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:57:14 |

US3092245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

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 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered empty.       | Shraddha Dubal (b) (4) | 27 Aug 2020 18:57:14 |

US3092245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 27 Aug 2020 18:57:14 |



US3092245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                              | Time (GMT)           |
|----------------------------|-----------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                  | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '27 Aug 2020' | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:57:14 |

US3092245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '13:50'      | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:57:14 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered '27 Aug 2020 13:50' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[Which arm was used to give treatment?](#)

| Audit                              | User                   | Time (GMT)           |
|------------------------------------|------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded.          | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered 'Left Arm (LEFT ARM)' | Shraddha Dubal (b) (4) | 27 Aug 2020 18:57:14 |

US3092245

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'ONCE' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[What was the route of administration for the study treatment?](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'INTRAMUSCULAR' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:08

[Was the sample collected?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 05 Nov 2020 23:55:17 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '27 Aug 2020' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:55:17 |



**US3092245**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '13:43'      | Marissa Cervenka (b) (4) | 05 Nov 2020 23:55:17 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered '27 Aug 2020 13:43' | System           | 05 Nov 2020 23:55:17 |

US3092245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:10:08

Collection date (*dd MMM yyyy*)

| Audit                      | User                                | Time (GMT)           |
|----------------------------|-------------------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered '27 Aug 2020' | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:55:42 |

US3092245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:10:08

[Lab Test](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:55:42 |

US3092245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:10:08

[Was the sample collected?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:55:42 |

US3092245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:10:08

Collection time (00:00 - 23:59)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered '13:39'      | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:55:42 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered '27 Aug 2020 13:39' | System           | 05 Nov 2020 23:55:42 |

US3092245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:10:08

[Lab Test](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:55:42 |



US3092245

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:10:08

[Was the sample collected?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>Marissa Cervenka (b) (4) | 05 Nov 2020 23:55:42 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:10:08**

**Collection time (00:00 - 23:59)**

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered empty.       | Marissa Cervenka (b) (4) | 05 Nov 2020 23:55:42 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Collection date and time \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered empty. | System           | 05 Nov 2020 23:55:42 |

US3092245

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:10:08

[Is the participant continuing to the next visit?](#)

| Audit                     | User                              | Time (GMT)           |
|---------------------------|-----------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                  | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Shraddha Dubal (b) (4) | 27 Aug 2020 18:57:23 |

**US3092245**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'I'  | System           | 27 Aug 2020 18:57:23 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:29:42', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37f9954e-024c-4652-bba9-48f798700507' | System           | 27 Aug 2020 19:30:22 |
| User entered 'Yes (Y)'   | System           | 27 Aug 2020 19:30:22 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:29:51', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37f9954e-024c-4652-bba9-48f798700507' User entered '97.3' | System           | 27 Aug 2020 19:30:22 |
|  | System           | 27 Aug 2020 19:30:22 |



US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:29:59', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37f9954e-024c-4652-bba9-48f798700507' | System           | 27 Aug 2020 19:30:22 |
| User entered 'Yes (Y)'   | System           | 27 Aug 2020 19:30:22 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:30:08', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37f9954e-024c-4652-bba9-48f798700507' | System           | 27 Aug 2020 19:30:22 |
| User entered '0'   | System           | 27 Aug 2020 19:30:22 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

To **PREVENT** pain or fever from occurring

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 25 Feb 2021 15:55:38 |
| User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'DONE' (Site from System). | (b) (4), (b) (6)         | 09 Nov 2020 21:58:39 |
| User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:30:08', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37f9954e-024c-4652-bba9-48f798700507'                                | Marissa Cervenka (b) (4) | 06 Nov 2020 00:39:35 |
| User entered '1'   | System                   | 27 Aug 2020 19:30:22 |

**US3092245**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:30:18', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37f9954e-024c-4652-bba9-48f798700507' | System           | 27 Aug 2020 19:30:22 |
| User entered '27 Aug 2020 14:30'   | System           | 27 Aug 2020 19:30:22 |

**US3092245**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '27 Aug 2020 14:10' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '27 Aug 2020 16:40' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.                                | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 1, after vaccination (at home)' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T23:37:16', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '0233e3ec-1e38-41a4-814a-0c649009fd21' | System           | 28 Aug 2020 04:38:35 |
| User entered 'Yes (Y)'   | System           | 28 Aug 2020 04:38:35 |



US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T23:37:43', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '0233e3ec-1e38-41a4-814a-0c649009fd21' | System           | 28 Aug 2020 04:38:35 |
| User entered '97.6'  | System           | 28 Aug 2020 04:38:35 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T23:37:54', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '0233e3ec-1e38-41a4-814a-0c649009fd21' | System           | 28 Aug 2020 04:38:35 |
| User entered 'Yes (Y)'   | System           | 28 Aug 2020 04:38:35 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T23:38:16', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '0233e3ec-1e38-41a4-814a-0c649009fd21' | System           | 28 Aug 2020 04:38:35 |
| User entered '0'   | System           | 28 Aug 2020 04:38:35 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

To **PREVENT** pain or fever from occurring

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 25 Feb 2021 15:55:38 |
| User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'DONE' (Site from System). | Marissa Cervenka (b) (4) | 06 Nov 2020 00:40:35 |
| User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).   | System                   | 28 Aug 2020 04:38:35 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T23:38:16', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '0233e3ec-1e38-41a4-814a-0c649009fd21'   | System                   | 28 Aug 2020 04:38:35 |
| User entered '1'   | System                   | 28 Aug 2020 04:38:35 |

**US3092245**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T23:38:32', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '0233e3ec-1e38-41a4-814a-0c649009fd21' | System           | 28 Aug 2020 04:38:35 |
| User entered '27 Aug 2020 23:38'   | System           | 28 Aug 2020 04:38:35 |

**US3092245**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '27 Aug 2020 17:35' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '28 Aug 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 2' | System           | 27 Aug 2020 18:57:14 |



US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:19:56', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '1ed3cc42-84d8-4d3b-b95b-5d8993562ba6' | System           | 28 Aug 2020 20:21:01 |
| User entered 'Yes (Y)'   | System           | 28 Aug 2020 20:21:01 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:20:11', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '1ed3cc42-84d8-4d3b-b95b-5d8993562ba6' | System           | 28 Aug 2020 20:21:01 |
| User entered '97.6'  | System           | 28 Aug 2020 20:21:01 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:20:18', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '1ed3cc42-84d8-4d3b-b95b-5d8993562ba6' | System           | 28 Aug 2020 20:21:01 |
| User entered 'Yes (Y)'   | System           | 28 Aug 2020 20:21:01 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 25 Feb 2021 15:55:38 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'DONE' (Site from System). | (b) (4), (b) (6)         | 09 Nov 2020 21:59:45 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:20:36', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '1ed3cc42-84d8-4d3b-b95b-5d8993562ba6'                              | Marissa Cervenka (b) (4) | 06 Nov 2020 00:41:34 |
| User entered '1'   | System                   | 28 Aug 2020 20:21:01 |
|  | System                   | 28 Aug 2020 20:21:01 |
|  | System                   | 28 Aug 2020 20:21:01 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

To **PREVENT** pain or fever from occurring

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:20:36', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '1ed3cc42-84d8-4d3b-b95b-5d8993562ba6' | System           | 28 Aug 2020 20:21:01 |
| User entered '0'   | System           | 28 Aug 2020 20:21:01 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:20:47', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '1ed3cc42-84d8-4d3b-b95b-5d8993562ba6' | System           | 28 Aug 2020 20:21:01 |
| User entered '28 Aug 2020 15:20'   | System           | 28 Aug 2020 20:21:01 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '28 Aug 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Aug 2020 11:59' | System           | 27 Aug 2020 18:57:14 |



US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 3' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:50:06', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e7cc7f26-1c35-44d5-9471-f40da058363f' | System           | 29 Aug 2020 21:50:53 |
| User entered 'Yes (Y)'   | System           | 29 Aug 2020 21:50:53 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:50:21', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e7cc7f26-1c35-44d5-9471-f40da058363f' | System           | 29 Aug 2020 21:50:53 |
| User entered '98.2'  | System           | 29 Aug 2020 21:50:53 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:50:29', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e7cc7f26-1c35-44d5-9471-f40da058363f' | System           | 29 Aug 2020 21:50:53 |
| User entered 'No (N)'  | System           | 29 Aug 2020 21:50:53 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:10:08

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:50:48', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e7cc7f26-1c35-44d5-9471-f40da058363f' | System           | 29 Aug 2020 21:50:53 |
| User entered '29 Aug 2020 16:50'   | System           | 29 Aug 2020 21:50:53 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Aug 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '30 Aug 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 4' | System           | 27 Aug 2020 18:57:14 |



US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:55:05', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '602d227c-ed7e-4cf4-b69f-93df79f8710f' | System           | 31 Aug 2020 11:56:17 |
| User entered 'Yes (Y)'   | System           | 31 Aug 2020 11:56:17 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:55:51', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '602d227c-ed7e-4cf4-b69f-93df79f8710f' User entered '96.9' | System           | 31 Aug 2020 11:56:17 |
|  | System           | 31 Aug 2020 11:56:17 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:56:03', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '602d227c-ed7e-4cf4-b69f-93df79f8710f' | System           | 31 Aug 2020 11:56:17 |
| User entered 'No (N)'  | System           | 31 Aug 2020 11:56:17 |

**US3092245**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:56:13', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '602d227c-ed7e-4cf4-b69f-93df79f8710f' | System           | 31 Aug 2020 11:56:17 |
| User entered '31 Aug 2020 06:56'   | System           | 31 Aug 2020 11:56:17 |

**US3092245**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '30 Aug 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '31 Aug 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 5' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T12:52:34', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b9eb50bb-8a0d-41db-9353-b2aa6a2d3cd9' | System           | 31 Aug 2020 17:56:07 |
| User entered 'Yes (Y)'   | System           | 31 Aug 2020 17:56:07 |



US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T12:52:44', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b9eb50bb-8a0d-41db-9353-b2aa6a2d3cd9' User entered '97.2' | System           | 31 Aug 2020 17:56:07 |
|  | System           | 31 Aug 2020 17:56:07 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T12:52:50', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b9eb50bb-8a0d-41db-9353-b2aa6a2d3cd9' | System           | 31 Aug 2020 17:56:07 |
| User entered 'No (N)'  | System           | 31 Aug 2020 17:56:07 |

**US3092245**

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

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T12:52:57', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b9eb50bb-8a0d-41db-9353-b2aa6a2d3cd9' | System           | 31 Aug 2020 17:56:07 |
| User entered '31 Aug 2020 12:52'   | System           | 31 Aug 2020 17:56:07 |

**US3092245**

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

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '31 Aug 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '01 Sep 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 6' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:51:57', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'd9b530c0-4976-4db0-ac06-4a8ab0157eb6' | System           | 01 Sep 2020 18:52:52 |
| User entered 'Yes (Y)'   | System           | 01 Sep 2020 18:52:52 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:52:33', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'd9b530c0-4976-4db0-ac06-4a8ab0157eb6' | System           | 01 Sep 2020 18:52:52 |
| User entered '98.6'  | System           | 01 Sep 2020 18:52:52 |



US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:52:38', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'd9b530c0-4976-4db0-ac06-4a8ab0157eb6' | System           | 01 Sep 2020 18:52:52 |
| User entered 'No (N)'  | System           | 01 Sep 2020 18:52:52 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:52:47', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'd9b530c0-4976-4db0-ac06-4a8ab0157eb6' | System           | 01 Sep 2020 18:52:52 |
| User entered '01 Sep 2020 13:52'   | System           | 01 Sep 2020 18:52:52 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '01 Sep 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '02 Sep 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 7' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:56:54', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e32b63fd-87b9-4e89-8e09-c179888448cf' | System           | 02 Sep 2020 20:58:43 |
| User entered 'Yes (Y)'   | System           | 02 Sep 2020 20:58:43 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:57:44', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e32b63fd-87b9-4e89-8e09-c179888448cf' User entered '98.7' | System           | 02 Sep 2020 20:58:43 |
|  | System           | 02 Sep 2020 20:58:43 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:57:59', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e32b63fd-87b9-4e89-8e09-c179888448cf' | System           | 02 Sep 2020 20:58:43 |
| User entered 'Yes (Y)'   | System           | 02 Sep 2020 20:58:43 |



US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                    | 25 Feb 2021 15:55:38 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'DONE' (Site from System). | (b) (4), (b) (6)                    | 09 Nov 2020 22:00:23 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:58:22', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e32b63fd-87b9-4e89-8e09-c179888448cf' User entered '1'             | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 01:36:37 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).   | System                              | 02 Sep 2020 20:58:43 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:58:22', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e32b63fd-87b9-4e89-8e09-c179888448cf' User entered '1'  | System                              | 02 Sep 2020 20:58:43 |
| User entered '1'   | System                              | 02 Sep 2020 20:58:43 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

To **PREVENT** pain or fever from occurring

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:58:22', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e32b63fd-87b9-4e89-8e09-c179888448cf' | System           | 02 Sep 2020 20:58:43 |
| User entered '0'   | System           | 02 Sep 2020 20:58:43 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:58:40', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e32b63fd-87b9-4e89-8e09-c179888448cf' | System           | 02 Sep 2020 20:58:43 |
| User entered '02 Sep 2020 15:58'   | System           | 02 Sep 2020 20:58:43 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '02 Sep 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Sep 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 02 Sep 2020 20:58:43 |
| User entered 'Day 8' | System           | 02 Sep 2020 20:58:43 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |



US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Temperature\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Temperature\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Sep 2020 12:00' | System           | 02 Sep 2020 20:58:43 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 11:59' | System           | 02 Sep 2020 20:58:43 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 02 Sep 2020 20:58:43 |
| User entered 'Day 9' | System           | 02 Sep 2020 20:58:43 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |



US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 09 Jun 2021 15:10:08

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Temperature\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Temperature\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 12:00' | System           | 02 Sep 2020 20:58:43 |

**US3092245**

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

**Form: Temperature\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '05 Sep 2020 11:59' | System           | 02 Sep 2020 20:58:43 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 27 Aug 2020 18:57:14 |



US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:31:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'ff82f750-2526-4edc-aed7-b70d8269341b' | System           | 27 Aug 2020 19:31:37 |
| User entered 'None (1)'  | System           | 27 Aug 2020 19:31:37 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:31:13', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'ff82f750-2526-4edc-aed7-b70d8269341b' | System           | 27 Aug 2020 19:31:37 |
| User entered 'No (N)'  | System           | 27 Aug 2020 19:31:37 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:31:18', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'ff82f750-2526-4edc-aed7-b70d8269341b' | System           | 27 Aug 2020 19:31:37 |
| User entered 'No (N)'  | System           | 27 Aug 2020 19:31:37 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:31:24', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'ff82f750-2526-4edc-aed7-b70d8269341b' | System           | 27 Aug 2020 19:31:37 |
| User entered 'None (1)'  | System           | 27 Aug 2020 19:31:37 |

**US3092245**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:31:34', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'ff82f750-2526-4edc-aed7-b70d8269341b' | System           | 27 Aug 2020 19:31:37 |
| User entered '27 Aug 2020 14:31'   | System           | 27 Aug 2020 19:31:37 |

**US3092245**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '27 Aug 2020 14:10' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '27 Aug 2020 16:40' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.                                | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 1, after vaccination (at home)' | System           | 27 Aug 2020 18:57:14 |



US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T23:38:50', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '35602883-7109-45d5-8392-9ccecbee589f' | System           | 28 Aug 2020 04:39:37 |
| User entered 'None (1)'  | System           | 28 Aug 2020 04:39:37 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T23:38:55', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '35602883-7109-45d5-8392-9ccecbee589f' | System           | 28 Aug 2020 04:39:37 |
| User entered 'No (N)'  | System           | 28 Aug 2020 04:39:37 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T23:38:59', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '35602883-7109-45d5-8392-9ccecbee589f' | System           | 28 Aug 2020 04:39:37 |
| User entered 'No (N)'  | System           | 28 Aug 2020 04:39:37 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T23:39:18', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '35602883-7109-45d5-8392-9ccecbee589f' | System           | 28 Aug 2020 04:39:37 |
| User entered 'None (1)'  | System           | 28 Aug 2020 04:39:37 |

**US3092245**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T23:39:33', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '35602883-7109-45d5-8392-9ccecbee589f' | System           | 28 Aug 2020 04:39:37 |
| User entered '27 Aug 2020 23:39'   | System           | 28 Aug 2020 04:39:37 |

**US3092245**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '27 Aug 2020 17:35' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '28 Aug 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 2' | System           | 27 Aug 2020 18:57:14 |



US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:21:13', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'daace61c-5949-4725-bea3-4e4d201e4bfd' | System           | 28 Aug 2020 20:21:59 |
| User entered 'None (1)'  | System           | 28 Aug 2020 20:21:59 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:10:08

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:21:25', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'daace61c-5949-4725-bea3-4e4d201e4bfd' | System           | 28 Aug 2020 20:21:59 |
| User entered 'No (N)'  | System           | 28 Aug 2020 20:21:59 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:21:37', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'daace61c-5949-4725-bea3-4e4d201e4bfd' | System           | 28 Aug 2020 20:21:59 |
| User entered 'No (N)'  | System           | 28 Aug 2020 20:21:59 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:21:49', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'daace61c-5949-4725-bea3-4e4d201e4bfd' | System           | 28 Aug 2020 20:21:59 |
| User entered 'None (1)'  | System           | 28 Aug 2020 20:21:59 |

**US3092245**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:21:56', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'daace61c-5949-4725-bea3-4e4d201e4bfd' | System           | 28 Aug 2020 20:21:59 |
| User entered '28 Aug 2020 15:21'   | System           | 28 Aug 2020 20:21:59 |

**US3092245**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '28 Aug 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Aug 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 3' | System           | 27 Aug 2020 18:57:14 |



US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:51:09', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '46142be5-8565-43dd-b4b9-5e78d1980ecc' | System           | 29 Aug 2020 21:51:42 |
| User entered 'None (1)'  | System           | 29 Aug 2020 21:51:42 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:51:12', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '46142be5-8565-43dd-b4b9-5e78d1980ecc' | System           | 29 Aug 2020 21:51:42 |
| User entered 'No (N)'  | System           | 29 Aug 2020 21:51:42 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:51:17', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '46142be5-8565-43dd-b4b9-5e78d1980ecc' | System           | 29 Aug 2020 21:51:42 |
| User entered 'No (N)'  | System           | 29 Aug 2020 21:51:42 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:51:29', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '46142be5-8565-43dd-b4b9-5e78d1980ecc' | System           | 29 Aug 2020 21:51:42 |
| User entered 'None (1)'  | System           | 29 Aug 2020 21:51:42 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:10:08

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:51:39', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '46142be5-8565-43dd-b4b9-5e78d1980ecc' | System           | 29 Aug 2020 21:51:42 |
| User entered '29 Aug 2020 16:51'   | System           | 29 Aug 2020 21:51:42 |

**US3092245**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Aug 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '30 Aug 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 4' | System           | 27 Aug 2020 18:57:14 |



US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:56:38', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '08e87048-6ed4-4828-93bb-bef9b4b6f7a4' | System           | 31 Aug 2020 11:57:30 |
| User entered 'None (1)'  | System           | 31 Aug 2020 11:57:30 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:56:47', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '08e87048-6ed4-4828-93bb-bef9b4b6f7a4' | System           | 31 Aug 2020 11:57:30 |
| User entered 'No (N)'  | System           | 31 Aug 2020 11:57:30 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:56:53', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '08e87048-6ed4-4828-93bb-bef9b4b6f7a4' | System           | 31 Aug 2020 11:57:30 |
| User entered 'No (N)'  | System           | 31 Aug 2020 11:57:30 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:57:11', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '08e87048-6ed4-4828-93bb-bef9b4b6f7a4' | System           | 31 Aug 2020 11:57:30 |
| User entered 'None (1)'  | System           | 31 Aug 2020 11:57:30 |

**US3092245**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:57:25', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '08e87048-6ed4-4828-93bb-bef9b4b6f7a4' | System           | 31 Aug 2020 11:57:30 |
| User entered '31 Aug 2020 06:57'   | System           | 31 Aug 2020 11:57:30 |

**US3092245**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '30 Aug 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '31 Aug 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 5' | System           | 27 Aug 2020 18:57:14 |



US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T12:53:04', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '5d2186bc-f6f7-41cb-9e51-d3691baf1329' | System           | 31 Aug 2020 17:57:35 |
| User entered 'None (1)'  | System           | 31 Aug 2020 17:57:35 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:10:08

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T12:53:08', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '5d2186bc-f6f7-41cb-9e51-d3691baf1329' | System           | 31 Aug 2020 17:57:35 |
| User entered 'No (N)'  | System           | 31 Aug 2020 17:57:35 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T12:53:12', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '5d2186bc-f6f7-41cb-9e51-d3691baf1329' | System           | 31 Aug 2020 17:57:35 |
| User entered 'No (N)'  | System           | 31 Aug 2020 17:57:35 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T12:53:16', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '5d2186bc-f6f7-41cb-9e51-d3691baf1329' | System           | 31 Aug 2020 17:57:35 |
| User entered 'None (1)'  | System           | 31 Aug 2020 17:57:35 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:10:08

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T12:53:23', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '5d2186bc-f6f7-41cb-9e51-d3691baf1329' | System           | 31 Aug 2020 17:57:35 |
| User entered '31 Aug 2020 12:53'   | System           | 31 Aug 2020 17:57:35 |

**US3092245**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '31 Aug 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '01 Sep 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 6' | System           | 27 Aug 2020 18:57:14 |



US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:52:58', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '0744cf64-f758-4754-8c87-3839e5ac3b3f' | System           | 01 Sep 2020 18:53:40 |
| User entered 'None (1)'  | System           | 01 Sep 2020 18:53:40 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:10:08

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:53:18', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '0744cf64-f758-4754-8c87-3839e5ac3b3f' | System           | 01 Sep 2020 18:53:40 |
| User entered 'No (N)'  | System           | 01 Sep 2020 18:53:40 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:53:22', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '0744cf64-f758-4754-8c87-3839e5ac3b3f' | System           | 01 Sep 2020 18:53:40 |
| User entered 'No (N)'  | System           | 01 Sep 2020 18:53:40 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:53:31', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '0744cf64-f758-4754-8c87-3839e5ac3b3f' | System           | 01 Sep 2020 18:53:40 |
| User entered 'None (1)'  | System           | 01 Sep 2020 18:53:40 |

**US3092245**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:53:37', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '0744cf64-f758-4754-8c87-3839e5ac3b3f' | System           | 01 Sep 2020 18:53:40 |
| User entered '01 Sep 2020 13:53'   | System           | 01 Sep 2020 18:53:40 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:10:08

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '01 Sep 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '02 Sep 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 7' | System           | 27 Aug 2020 18:57:14 |



US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:58:53', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '98f7f474-307e-4bd1-82fb-05bbe730187e' | System           | 02 Sep 2020 20:59:37 |
| User entered 'None (1)'  | System           | 02 Sep 2020 20:59:37 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:58:59', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '98f7f474-307e-4bd1-82fb-05bbe730187e' | System           | 02 Sep 2020 20:59:37 |
| User entered 'No (N)'  | System           | 02 Sep 2020 20:59:37 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:59:04', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '98f7f474-307e-4bd1-82fb-05bbe730187e' | System           | 02 Sep 2020 20:59:37 |
| User entered 'No (N)'  | System           | 02 Sep 2020 20:59:37 |

US3092245

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:59:14', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '98f7f474-307e-4bd1-82fb-05bbe730187e' | System           | 02 Sep 2020 20:59:37 |
| User entered 'None (1)'  | System           | 02 Sep 2020 20:59:37 |

**US3092245**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:59:32', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '98f7f474-307e-4bd1-82fb-05bbe730187e' | System           | 02 Sep 2020 20:59:37 |
| User entered '02 Sep 2020 15:59'   | System           | 02 Sep 2020 20:59:37 |

**US3092245**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '02 Sep 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Sep 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 27 Aug 2020 18:57:14 |



**US3092245**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:31:46', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b0360e7d-e39b-4ac1-a74e-041ae69c702c' | System           | 27 Aug 2020 19:32:16 |
| User entered 'None (0)'  | System           | 27 Aug 2020 19:32:16 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:31:49', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b0360e7d-e39b-4ac1-a74e-041ae69c702c' | System           | 27 Aug 2020 19:32:16 |
| User entered 'None (0)'  | System           | 27 Aug 2020 19:32:16 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:31:53', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b0360e7d-e39b-4ac1-a74e-041ae69c702c' | System           | 27 Aug 2020 19:32:16 |
| User entered 'None (0)'  | System           | 27 Aug 2020 19:32:16 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:31:56', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b0360e7d-e39b-4ac1-a74e-041ae69c702c' | System           | 27 Aug 2020 19:32:16 |
| User entered 'None (0)'  | System           | 27 Aug 2020 19:32:16 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:31:58', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b0360e7d-e39b-4ac1-a74e-041ae69c702c' | System           | 27 Aug 2020 19:32:16 |
| User entered 'None (0)'  | System           | 27 Aug 2020 19:32:16 |

**US3092245**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:32:01', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b0360e7d-e39b-4ac1-a74e-041ae69c702c' | System           | 27 Aug 2020 19:32:16 |
| User entered 'None (0)'  | System           | 27 Aug 2020 19:32:16 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:32:08', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b0360e7d-e39b-4ac1-a74e-041ae69c702c' | System           | 27 Aug 2020 19:32:16 |
| User entered 'No (N)'  | System           | 27 Aug 2020 19:32:16 |

**US3092245**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-27T14:32:14', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b0360e7d-e39b-4ac1-a74e-041ae69c702c' | System           | 27 Aug 2020 19:32:16 |
| User entered '27 Aug 2020 14:32'   | System           | 27 Aug 2020 19:32:16 |



**US3092245**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '27 Aug 2020 14:10' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '27 Aug 2020 16:40' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.                                | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 1, after vaccination (at home)' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T08:50:30', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8be1c010-6112-43a3-9439-d0f9e359ca96' | System           | 28 Aug 2020 13:51:52 |
| User entered 'None (0)'  | System           | 28 Aug 2020 13:51:52 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T08:50:55', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8be1c010-6112-43a3-9439-d0f9e359ca96' | System           | 28 Aug 2020 13:51:52 |
| User entered 'None (0)'  | System           | 28 Aug 2020 13:51:52 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T08:51:01', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8be1c010-6112-43a3-9439-d0f9e359ca96' | System           | 28 Aug 2020 13:51:52 |
| User entered 'None (0)'  | System           | 28 Aug 2020 13:51:52 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T08:51:11', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8be1c010-6112-43a3-9439-d0f9e359ca96' | System           | 28 Aug 2020 13:51:52 |
| User entered 'None (0)'  | System           | 28 Aug 2020 13:51:52 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T08:51:14', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8be1c010-6112-43a3-9439-d0f9e359ca96' | System           | 28 Aug 2020 13:51:52 |
| User entered 'None (0)'  | System           | 28 Aug 2020 13:51:52 |



**US3092245**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T08:51:20', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8be1c010-6112-43a3-9439-d0f9e359ca96' | System           | 28 Aug 2020 13:51:52 |
| User entered 'None (0)'  | System           | 28 Aug 2020 13:51:52 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T08:51:36', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8be1c010-6112-43a3-9439-d0f9e359ca96' | System           | 28 Aug 2020 13:51:52 |
| User entered 'No (N)'  | System           | 28 Aug 2020 13:51:52 |

**US3092245**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T08:51:49', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8be1c010-6112-43a3-9439-d0f9e359ca96' | System           | 28 Aug 2020 13:51:52 |
| User entered '28 Aug 2020 08:51'   | System           | 28 Aug 2020 13:51:52 |

**US3092245**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '27 Aug 2020 17:35' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '28 Aug 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 2' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:22:05', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '20fce0c4-04d3-4154-a733-f357624b8437' | System           | 28 Aug 2020 20:24:29 |
| User entered 'None (0)'  | System           | 28 Aug 2020 20:24:29 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:22:38', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '20fce0c4-04d3-4154-a733-f357624b8437' | System           | 28 Aug 2020 20:24:29 |
| User entered 'Some interference with activity (2)'   | System           | 28 Aug 2020 20:24:29 |



US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:22:52', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '20fce0c4-04d3-4154-a733-f357624b8437' | System           | 28 Aug 2020 20:24:29 |
| User entered 'None (0)'  | System           | 28 Aug 2020 20:24:29 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:23:05', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '20fce0c4-04d3-4154-a733-f357624b8437' | System           | 28 Aug 2020 20:24:29 |
| User entered 'None (0)'  | System           | 28 Aug 2020 20:24:29 |

**US3092245**

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

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:23:16', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '20fce0c4-04d3-4154-a733-f357624b8437' | System           | 28 Aug 2020 20:24:29 |
| User entered 'None (0)'  | System           | 28 Aug 2020 20:24:29 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:23:21', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '20fce0c4-04d3-4154-a733-f357624b8437' | System           | 28 Aug 2020 20:24:29 |
| User entered 'None (0)'  | System           | 28 Aug 2020 20:24:29 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:23:31', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '20fce0c4-04d3-4154-a733-f357624b8437' | System           | 28 Aug 2020 20:24:29 |
| User entered 'No (N)'  | System           | 28 Aug 2020 20:24:29 |

**US3092245**

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

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-28T15:24:23', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '20fce0c4-04d3-4154-a733-f357624b8437' | System           | 28 Aug 2020 20:24:29 |
| User entered '28 Aug 2020 15:24'   | System           | 28 Aug 2020 20:24:29 |

**US3092245**

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

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '28 Aug 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Aug 2020 11:59' | System           | 27 Aug 2020 18:57:14 |



**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 3' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:51:50', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6e3e0b77-2651-4654-85dc-7ccfc4ce82b6' | System           | 29 Aug 2020 21:53:24 |
| User entered 'None (0)'  | System           | 29 Aug 2020 21:53:24 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:52:13', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6e3e0b77-2651-4654-85dc-7ccfc4ce82b6' | System           | 29 Aug 2020 21:53:24 |
| User entered 'None (0)'  | System           | 29 Aug 2020 21:53:24 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:52:24', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6e3e0b77-2651-4654-85dc-7ccfc4ce82b6' | System           | 29 Aug 2020 21:53:24 |
| User entered 'None (0)'  | System           | 29 Aug 2020 21:53:24 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:52:43', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6e3e0b77-2651-4654-85dc-7ccfc4ce82b6' | System           | 29 Aug 2020 21:53:24 |
| User entered 'None (0)'  | System           | 29 Aug 2020 21:53:24 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:52:40', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6e3e0b77-2651-4654-85dc-7ccfc4ce82b6' | System           | 29 Aug 2020 21:53:24 |
| User entered 'Some interference with activity or >2 episodes/24 hours (2)'   | System           | 29 Aug 2020 21:53:24 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:52:49', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6e3e0b77-2651-4654-85dc-7ccfc4ce82b6' | System           | 29 Aug 2020 21:53:24 |
| User entered 'None (0)'  | System           | 29 Aug 2020 21:53:24 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:52:59', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6e3e0b77-2651-4654-85dc-7ccfc4ce82b6' | System           | 29 Aug 2020 21:53:24 |
| User entered 'No (N)'  | System           | 29 Aug 2020 21:53:24 |



**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-29T16:53:18', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6e3e0b77-2651-4654-85dc-7ccfc4ce82b6' | System           | 29 Aug 2020 21:53:24 |
| User entered '29 Aug 2020 16:53'   | System           | 29 Aug 2020 21:53:24 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Aug 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '30 Aug 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 4' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:57:37', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b270c989-b05f-471f-8b0c-5b37a0064036' | System           | 31 Aug 2020 11:58:58 |
| User entered 'None (0)'  | System           | 31 Aug 2020 11:58:58 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:58:04', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b270c989-b05f-471f-8b0c-5b37a0064036' | System           | 31 Aug 2020 11:58:58 |
| User entered 'No interference with activity (1)'   | System           | 31 Aug 2020 11:58:58 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:58:19', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b270c989-b05f-471f-8b0c-5b37a0064036' | System           | 31 Aug 2020 11:58:58 |
| User entered 'None (0)'  | System           | 31 Aug 2020 11:58:58 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:58:24', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b270c989-b05f-471f-8b0c-5b37a0064036' | System           | 31 Aug 2020 11:58:58 |
| User entered 'None (0)'  | System           | 31 Aug 2020 11:58:58 |



**US3092245**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:58:29', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b270c989-b05f-471f-8b0c-5b37a0064036' | System           | 31 Aug 2020 11:58:58 |
| User entered 'None (0)'  | System           | 31 Aug 2020 11:58:58 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:58:32', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b270c989-b05f-471f-8b0c-5b37a0064036' | System           | 31 Aug 2020 11:58:58 |
| User entered 'None (0)'  | System           | 31 Aug 2020 11:58:58 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:58:41', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b270c989-b05f-471f-8b0c-5b37a0064036' | System           | 31 Aug 2020 11:58:58 |
| User entered 'No (N)'  | System           | 31 Aug 2020 11:58:58 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T06:58:55', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b270c989-b05f-471f-8b0c-5b37a0064036' | System           | 31 Aug 2020 11:58:58 |
| User entered '31 Aug 2020 06:58'   | System           | 31 Aug 2020 11:58:58 |

**US3092245**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '30 Aug 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '31 Aug 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 5' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T12:53:31', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '2c715170-d0d3-4797-8553-b5bc8d65b7be' | System           | 31 Aug 2020 18:08:16 |
| User entered 'None (0)'  | System           | 31 Aug 2020 18:08:16 |



US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T12:53:37', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '2c715170-d0d3-4797-8553-b5bc8d65b7be' | System           | 31 Aug 2020 18:08:16 |
| User entered 'None (0)'  | System           | 31 Aug 2020 18:08:16 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T12:53:41', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '2c715170-d0d3-4797-8553-b5bc8d65b7be' | System           | 31 Aug 2020 18:08:16 |
| User entered 'None (0)'  | System           | 31 Aug 2020 18:08:16 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T12:53:45', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '2c715170-d0d3-4797-8553-b5bc8d65b7be' | System           | 31 Aug 2020 18:08:16 |
| User entered 'None (0)'  | System           | 31 Aug 2020 18:08:16 |

**US3092245**

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

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T13:01:58', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '2c715170-d0d3-4797-8553-b5bc8d65b7be' | System           | 31 Aug 2020 18:08:16 |
| User entered 'None (0)'  | System           | 31 Aug 2020 18:08:16 |

**US3092245**

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

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T13:02:03', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '2c715170-d0d3-4797-8553-b5bc8d65b7be' | System           | 31 Aug 2020 18:08:16 |
| User entered 'None (0)'  | System           | 31 Aug 2020 18:08:16 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T13:02:11', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '2c715170-d0d3-4797-8553-b5bc8d65b7be' | System           | 31 Aug 2020 18:08:16 |
| User entered 'No (N)'  | System           | 31 Aug 2020 18:08:16 |

**US3092245**

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

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-08-31T13:02:18', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '2c715170-d0d3-4797-8553-b5bc8d65b7be' | System           | 31 Aug 2020 18:08:16 |
| User entered '31 Aug 2020 13:02'   | System           | 31 Aug 2020 18:08:16 |

**US3092245**

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

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '31 Aug 2020 12:00' | System           | 27 Aug 2020 18:57:14 |



**US3092245**

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

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '01 Sep 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 6' | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:53:45', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'df382fb4-63dc-4726-a8cc-d569928c13c3' | System           | 01 Sep 2020 18:54:39 |
| User entered 'None (0)'  | System           | 01 Sep 2020 18:54:39 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:53:49', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'df382fb4-63dc-4726-a8cc-d569928c13c3' | System           | 01 Sep 2020 18:54:39 |
| User entered 'None (0)'  | System           | 01 Sep 2020 18:54:39 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:53:55', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'df382fb4-63dc-4726-a8cc-d569928c13c3' | System           | 01 Sep 2020 18:54:39 |
| User entered 'None (0)'  | System           | 01 Sep 2020 18:54:39 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:53:58', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'df382fb4-63dc-4726-a8cc-d569928c13c3' | System           | 01 Sep 2020 18:54:39 |
| User entered 'None (0)'  | System           | 01 Sep 2020 18:54:39 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:54:01', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'df382fb4-63dc-4726-a8cc-d569928c13c3' | System           | 01 Sep 2020 18:54:39 |
| User entered 'None (0)'  | System           | 01 Sep 2020 18:54:39 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:54:20', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'df382fb4-63dc-4726-a8cc-d569928c13c3' | System           | 01 Sep 2020 18:54:39 |
| User entered 'Some interference with activity not requiring medical attention (2)'   | System           | 01 Sep 2020 18:54:39 |



US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:54:28', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'df382fb4-63dc-4726-a8cc-d569928c13c3' | System           | 01 Sep 2020 18:54:39 |
| User entered 'No (N)'  | System           | 01 Sep 2020 18:54:39 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-01T13:54:35', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'df382fb4-63dc-4726-a8cc-d569928c13c3' | System           | 01 Sep 2020 18:54:39 |
| User entered '01 Sep 2020 13:54'   | System           | 01 Sep 2020 18:54:39 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '01 Sep 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '02 Sep 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 7' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:59:46', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '08bd990e-6349-4b41-9b8b-bc7ef1d6dbd9' | System           | 02 Sep 2020 21:01:19 |
| User entered 'No interference with activity (1)'   | System           | 02 Sep 2020 21:01:19 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T15:59:58', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '08bd990e-6349-4b41-9b8b-bc7ef1d6dbd9' | System           | 02 Sep 2020 21:01:19 |
| User entered 'Some interference with activity (2)'   | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T16:00:08', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '08bd990e-6349-4b41-9b8b-bc7ef1d6dbd9' | System           | 02 Sep 2020 21:01:19 |
| User entered 'Some interference with activity (2)'   | System           | 02 Sep 2020 21:01:19 |



US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T16:00:17', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '08bd990e-6349-4b41-9b8b-bc7ef1d6dbd9' | System           | 02 Sep 2020 21:01:19 |
| User entered 'Some interference with activity (2)'   | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T16:00:23', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '08bd990e-6349-4b41-9b8b-bc7ef1d6dbd9' | System           | 02 Sep 2020 21:01:19 |
| User entered 'None (0)'  | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T16:00:30', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '08bd990e-6349-4b41-9b8b-bc7ef1d6dbd9' | System           | 02 Sep 2020 21:01:19 |
| User entered 'Some interference with activity not requiring medical attention (2)'   | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T16:00:42', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '08bd990e-6349-4b41-9b8b-bc7ef1d6dbd9' | System           | 02 Sep 2020 21:01:19 |
| User entered 'No (N)'  | System           | 02 Sep 2020 21:01:19 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-02T16:01:13', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '08bd990e-6349-4b41-9b8b-bc7ef1d6dbd9' | System           | 02 Sep 2020 21:01:19 |
| User entered '02 Sep 2020 16:01'   | System           | 02 Sep 2020 21:01:19 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '02 Sep 2020 12:00' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Sep 2020 11:59' | System           | 27 Aug 2020 18:57:14 |

**US3092245**

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

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 02 Sep 2020 21:01:19 |
| User entered 'Day 8' | System           | 02 Sep 2020 21:01:19 |



US3092245

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Sep 2020 12:00' | System           | 02 Sep 2020 21:01:19 |

**US3092245**

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

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 11:59' | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 02 Sep 2020 21:01:19 |
| User entered 'Day 9' | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Headache\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Headache\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 12:00' | System           | 02 Sep 2020 21:01:19 |



**US3092245**

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

**Form: Headache\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '05 Sep 2020 11:59' | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 02 Sep 2020 21:01:19 |
| User entered 'Day 8' | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Sep 2020 12:00' | System           | 02 Sep 2020 21:01:19 |

**US3092245**

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

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 11:59' | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 02 Sep 2020 21:01:19 |
| User entered 'Day 9' | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |



**US3092245**

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

**Form: Fatigue\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 09 Jun 2021 15:10:08

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 12:00' | System           | 02 Sep 2020 21:01:19 |

**US3092245**

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

**Form: Fatigue\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '05 Sep 2020 11:59' | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 02 Sep 2020 21:01:19 |
| User entered 'Day 8' | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 15:10:08

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: MuscleAche\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: MuscleAche\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Sep 2020 12:00' | System           | 02 Sep 2020 21:01:19 |

**US3092245**

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

**Form: MuscleAche\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 11:59' | System           | 02 Sep 2020 21:01:19 |



US3092245

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 02 Sep 2020 21:01:19 |
| User entered 'Day 9' | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(9)

Generated On: 09 Jun 2021 15:10:08

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: MuscleAche\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: MuscleAche\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 12:00' | System           | 02 Sep 2020 21:01:19 |

**US3092245**

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

**Form: MuscleAche\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '05 Sep 2020 11:59' | System           | 02 Sep 2020 21:01:19 |

**US3092245**

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

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 02 Sep 2020 21:01:19 |
| User entered 'Day 8' | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |



**US3092245**

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

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Sep 2020 12:00' | System           | 02 Sep 2020 21:01:19 |

**US3092245**

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

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 11:59' | System           | 02 Sep 2020 21:01:19 |

**US3092245**

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

**Form: JointsAche\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 02 Sep 2020 21:01:19 |
| User entered 'Day 9' | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |

**US3092245**

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

**Form: JointsAche\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: JointsAche\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 12:00' | System           | 02 Sep 2020 21:01:19 |

**US3092245**

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

**Form: JointsAche\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '05 Sep 2020 11:59' | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 01 Sep 2020 18:54:39 |
| User entered 'Day 8' | System           | 01 Sep 2020 18:54:39 |



US3092245

Folder: Diary Dose 1 (1)

Form: Chills\_Day(8)

Generated On: 09 Jun 2021 15:10:08

Select one response below to indicate the intensity of **CHILLS** you are experiencing

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |

**US3092245**

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

**Form: Chills\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Sep 2020 12:00' | System           | 01 Sep 2020 18:54:39 |

**US3092245**

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

**Form: Chills\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 11:59' | System           | 01 Sep 2020 18:54:39 |

**US3092245**

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

**Form: Chills\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 1 (1)

Form: Chills\_Day(9)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 02 Sep 2020 21:01:19 |
| User entered 'Day 9' | System           | 02 Sep 2020 21:01:19 |

US3092245

Folder: Diary Dose 1 (1)

Form: Chills\_Day(9)

Generated On: 09 Jun 2021 15:10:08

Select one response below to indicate the intensity of **CHILLS** you are experiencing

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |

**US3092245**

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

**Form: Chills\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 12:00' | System           | 02 Sep 2020 21:01:19 |

**US3092245**

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

**Form: Chills\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '05 Sep 2020 11:59' | System           | 02 Sep 2020 21:01:19 |



**US3092245**

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

**Form: Chills\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 01 Sep 2020 18:54:39 |
| User entered 'Day 8' | System           | 01 Sep 2020 18:54:39 |

US3092245

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |

**US3092245**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Sep 2020 12:00' | System           | 01 Sep 2020 18:54:39 |

**US3092245**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 11:59' | System           | 01 Sep 2020 18:54:39 |

**US3092245**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 02 Sep 2020 20:58:43 |
| User entered 'Day 9' | System           | 02 Sep 2020 20:58:43 |

US3092245

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |



**US3092245**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Sep 2020 12:00' | System           | 02 Sep 2020 20:58:43 |

**US3092245**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '05 Sep 2020 11:59' | System           | 02 Sep 2020 20:58:43 |

**US3092245**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Was Contact Attempted?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 12 Sep 2020 19:22:58 |

**US3092245**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '4 Sep 2020' | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 12 Sep 2020 19:22:58 |

**US3092245**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Please select one status for the follow-up contact](#)

| Audit  | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded.                          | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Contact Not Made (CONTACT NOT MADE)' | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 12 Sep 2020 19:22:58 |

**US3092245**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'left vm'    | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 12 Sep 2020 19:22:58 |

US3092245

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:08

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>destiny robinson (b) (4) | 12 Sep 2020 19:23:02 |



**US3092245**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'I'  | System           | 12 Sep 2020 19:23:02 |

**US3092245**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Was Contact Attempted?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 12 Sep 2020 19:23:26 |

**US3092245**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '11 Sep 2020' | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 12 Sep 2020 19:23:26 |

**US3092245**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Please select one status for the follow-up contact](#)

| Audit                                      | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded.                  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 12 Sep 2020 19:23:26 |

**US3092245**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 12 Sep 2020 19:23:26 |

US3092245

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:08

[Is the participant continuing to the next visit?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 12 Sep 2020 19:23:51 |

**US3092245**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'I'  | System           | 12 Sep 2020 19:23:51 |

**US3092245**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:31:32 |



**US3092245**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:31:32 |

**US3092245**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Please select one status for the follow-up contact](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:31:32 |

**US3092245**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:31:32 |

US3092245

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:08

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 29 Sep 2020 13:10:43 |

**US3092245**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'I'  | System           | 29 Sep 2020 13:10:43 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 29 Sep 2020 19:54:14 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '29 Sep 2020' | Catina Adams (b) (4)   | 29 Sep 2020 19:54:14 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[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 23:19:38 |
| User signature succeeded.      | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Clinic (Clinic)' | Catina Adams (b) (4)   | 29 Sep 2020 19:54:14 |



**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'VISIT2' | System           | 29 Sep 2020 19:54:14 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)                | 03 Apr 2021 23:19:45 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Catina Adams (b) (4)<br>(b) (4) | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Were vital signs assessed?

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User closed query 'Data is required. Please complete.' (Site from System).             | (b) (4)                |                      |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                 | 30 Sep 2020 14:13:11 |
| User entered 'Yes (Y)' reason for change: Data Entry Error                             | Catina Adams (b) (4)   | 30 Sep 2020 14:13:11 |
| User opened query 'Data is required. Please complete.' (Site from System).             | (b) (4)                |                      |
| User entered empty.  | System                 | 29 Sep 2020 20:02:31 |
|  | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |
|  | (b) (4)                |                      |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

**Date of assessment (dd MMM yyyy)**

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.                                      | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '29 Sep 2020' reason for change: Data Entry Error | Catina Adams (b) (4)   | 30 Sep 2020 14:13:11 |
| User entered empty.  | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Time of assessment \(00:00-23:59\)](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '13:54' reason for change: Data Entry Error | Catina Adams (b) (4)   | 30 Sep 2020 14:13:11 |
| User entered empty.                                      | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered '29 Sep 2020 13:54' | System           | 30 Sep 2020 14:13:11 |
| User entered empty.              | System           | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Temperature (xxx.x)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '36.1' C reason for change: Data Entry Error | Catina Adams (b) (4)   | 30 Sep 2020 14:13:11 |
| User entered empty.                                       | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Route of measurement](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.                                      | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Oral (Oral)' reason for change: Data Entry Error | Catina Adams (b) (4)   | 30 Sep 2020 14:13:11 |
| User entered empty.  | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |



**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered empty.       | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Pulse \(xxx\)](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.                             | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '66' reason for change: Data Entry Error | (b) (4)                |                      |
|   | Catina Adams (b) (4)   | 30 Sep 2020 14:13:11 |
| User entered empty.                                   | (b) (4)                |                      |
|   | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |
|   | (b) (4)                |                      |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'bpm'  | System           | 30 Sep 2020 14:13:11 |
| User entered empty. | System           | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate \(xxx\)](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.                             | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '15' reason for change: Data Entry Error | Catina Adams (b) (4)   | 30 Sep 2020 14:13:11 |
| User entered empty.                                   | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'breaths/min' | System           | 30 Sep 2020 14:13:11 |
| User entered empty.        | System           | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Systolic Blood Pressure (xxx)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.                              | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '158' reason for change: Data Entry Error | Catina Adams (b) (4)   | 30 Sep 2020 14:13:11 |
| User entered empty.                                    | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'mmHg' | System           | 30 Sep 2020 14:13:11 |
| User entered empty. | System           | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Diastolic Blood Pressure (xxx)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.                                     | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.                             | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '72' reason for change: Data Entry Error | Catina Adams (b) (4)   | 30 Sep 2020 14:13:11 |
| User entered empty.                                   | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |



US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'mmHg' | System           | 30 Sep 2020 14:13:11 |
| User entered empty. | System           | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Timepoint](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                | 03 Apr 2021 23:19:45 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Catina Adams (b) (4)<br>(b) (4) | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

**Date of assessment (dd MMM yyyy)**

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '29 Sep 2020' | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

**Time of assessment (00:00-23:59)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '15:00'      | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered '29 Sep 2020 15:00' | System           | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Temperature (xxx.x)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '98.8' F     | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Route of measurement](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Oral (Oral)' | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |



**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered empty.       | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '78'         | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'bpm' | System           | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '18'         | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'breaths/min' | System           | 29 Sep 2020 20:02:31 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '138'        | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'mmHg' | System           | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Diastolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '84'         | Catina Adams (b) (4)   | 29 Sep 2020 20:02:31 |



US3092245

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Diastolic Blood Pressure units

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'mmHg' | System           | 29 Sep 2020 20:02:31 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:08

[Was the physical examination performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 29 Sep 2020 19:54:30 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:10:08**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '29 Sep 2020' | Catina Adams (b) (4)   | 29 Sep 2020 19:54:30 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[Was study treatment given?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 29 Sep 2020 19:53:45 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[If No, reason not given](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered empty.       | Catina Adams (b) (4)   | 29 Sep 2020 19:53:45 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

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 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered empty.       | Catina Adams (b) (4)   | 29 Sep 2020 19:53:45 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[What was the study treatment?](#)

| Audit                               | User             | Time (GMT)           |
|-------------------------------------|------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'MRNA-1273 OR PLACEBO' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '29 Sep 2020' | Catina Adams (b) (4)   | 29 Sep 2020 19:53:45 |



US3092245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '14:28'      | Catina Adams (b) (4)   | 29 Sep 2020 19:53:45 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered '29 Sep 2020 14:28' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[Which arm was used to give treatment?](#)

| Audit                              | User                   | Time (GMT)           |
|------------------------------------|------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded.          | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Left Arm (LEFT ARM)' | Catina Adams (b) (4)   | 29 Sep 2020 19:53:45 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'ONCE' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'INTRAMUSCULAR' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:08

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 29 Sep 2020 20:00:35 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:08

Collection date (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '29 Sep 2020' | Catina Adams (b) (4)   | 29 Sep 2020 20:00:35 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

**Collection time (00:00-23:59)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '14:25'      | Catina Adams (b) (4)   | 29 Sep 2020 20:00:35 |



**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered '29 Sep 2020 14:25' | System           | 29 Sep 2020 20:00:35 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:10:08

Collection date (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '29 Sep 2020' | Catina Adams (b) (4)   | 29 Sep 2020 20:01:04 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Lab Test](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 03 Apr 2021 23:19:38 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Catina Adams (b) (4)<br>(b) (4) | 29 Sep 2020 20:01:04 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 29 Sep 2020 20:01:04 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:10:08**

**Collection time (00:00 - 23:59)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '14:20'      | Catina Adams (b) (4)   | 29 Sep 2020 20:01:04 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered '29 Sep 2020 14:20' | System           | 29 Sep 2020 20:01:04 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Lab Test](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                | 03 Apr 2021 23:19:38 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Catina Adams (b) (4)<br>(b) (4) | 29 Sep 2020 20:01:04 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:10:08

[Was the sample collected?](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                           | 03 Apr 2021 23:19:38 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)                     | 31 Mar 2021 16:41:20 |
| Signature has been broken.                                | (b) (4)<br>(b) (4), (b) (6)                | 29 Mar 2021 14:28:43 |
| User entered 'No (N)' reason for change: Data Entry Error |  | 29 Mar 2021 14:28:43 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)                     | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'                                    | (b) (4)<br>Catina Adams (b) (4)<br>(b) (4) | 29 Sep 2020 20:01:04 |



US3092245

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:10:08

Collection time (00:00 - 23:59)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                                      | (b) (4), (b) (6)                           | 03 Apr 2021 23:19:38 |
| User signature succeeded.                              | Valentine Ebuh (b) (4)                     | 31 Mar 2021 16:41:20 |
| Signature has been broken.                             | (b) (4)<br>(b) (4), (b) (6)                | 29 Mar 2021 14:28:43 |
| User entered empty; reason for change Data Entry Error |  | 29 Mar 2021 14:28:43 |
| User signature succeeded.                              | Valentine Ebuh (b) (4)                     | 23 Feb 2021 03:47:48 |
| User entered '14:20'                                   | (b) (4)<br>Catina Adams (b) (4)<br>(b) (4) | 29 Sep 2020 20:01:04 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered empty.              | System           | 29 Mar 2021 14:28:43 |
| User entered '29 Sep 2020 14:20' | System           | 29 Sep 2020 20:01:04 |

US3092245

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:08

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 29 Sep 2020 19:53:53 |

**US3092245**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'I'  | System           | 29 Sep 2020 19:53:53 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:57:12', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a6f9bbb1-4f55-4baa-9155-3634e9aaf608' | System           | 29 Sep 2020 19:57:39 |
| User entered 'Yes (Y)'   | System           | 29 Sep 2020 19:57:39 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:57:23', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a6f9bbb1-4f55-4baa-9155-3634e9aaf608' | System           | 29 Sep 2020 19:57:39 |
| User entered '98.8'  | System           | 29 Sep 2020 19:57:39 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:57:28', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a6f9bbb1-4f55-4baa-9155-3634e9aaf608' | System           | 29 Sep 2020 19:57:39 |
| User entered 'No (N)'  | System           | 29 Sep 2020 19:57:39 |



**US3092245**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:57:33', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a6f9bbb1-4f55-4baa-9155-3634e9aaf608' | System           | 29 Sep 2020 19:57:39 |
| User entered '29 Sep 2020 14:57'   | System           | 29 Sep 2020 19:57:39 |

**US3092245**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Sep 2020 14:48' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Sep 2020 17:18' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.                                | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 1, after vaccination (at home)' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:38:38', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8d24652a-f939-459f-a31c-4a881b0f6d30' | System           | 30 Sep 2020 03:39:12 |
| User entered 'Yes (Y)'   | System           | 30 Sep 2020 03:39:12 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:38:48', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8d24652a-f939-459f-a31c-4a881b0f6d30' | System           | 30 Sep 2020 03:39:12 |
| User entered '98.5'  | System           | 30 Sep 2020 03:39:12 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:38:55', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8d24652a-f939-459f-a31c-4a881b0f6d30' | System           | 30 Sep 2020 03:39:12 |
| User entered 'No (N)'  | System           | 30 Sep 2020 03:39:12 |

**US3092245**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:39:11', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8d24652a-f939-459f-a31c-4a881b0f6d30' | System           | 30 Sep 2020 03:39:12 |
| User entered '29 Sep 2020 22:39'   | System           | 30 Sep 2020 03:39:12 |



**US3092245**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Sep 2020 18:13' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '30 Sep 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 2' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:00:15', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a39086ab-ec05-4a50-9f6f-8b8c0ce0aaad' | System           | 01 Oct 2020 05:01:09 |
| User entered 'Yes (Y)'   | System           | 01 Oct 2020 05:01:09 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:00:25', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a39086ab-ec05-4a50-9f6f-8b8c0ce0aaad' | System           | 01 Oct 2020 05:01:09 |
| User entered '98.2'  | System           | 01 Oct 2020 05:01:09 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:00:32', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a39086ab-ec05-4a50-9f6f-8b8c0ce0aaad' | System           | 01 Oct 2020 05:01:09 |
| User entered 'Yes (Y)'   | System           | 01 Oct 2020 05:01:09 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 25 Feb 2021 15:55:38 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'DONE' (Site from System). | (b) (4), (b) (6)         | 09 Nov 2020 22:01:12 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).   | Marissa Cervenka (b) (4) | 06 Nov 2020 00:39:50 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:00:50', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a39086ab-ec05-4a50-9f6f-8b8c0ce0aaad'   | (b) (4)                  |                      |
| User entered '1'   | System                   | 01 Oct 2020 05:01:09 |
|  | System                   | 01 Oct 2020 05:01:09 |
|  | System                   | 01 Oct 2020 05:01:09 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

To **PREVENT** pain or fever from occurring

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:00:50', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a39086ab-ec05-4a50-9f6f-8b8c0ce0aaad' | System           | 01 Oct 2020 05:01:09 |
| User entered '0'   | System           | 01 Oct 2020 05:01:09 |



**US3092245**

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

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:01:02', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a39086ab-ec05-4a50-9f6f-8b8c0ce0aaad' | System           | 01 Oct 2020 05:01:09 |
| User entered '01 Oct 2020 00:01'   | System           | 01 Oct 2020 05:01:09 |

**US3092245**

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

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '30 Sep 2020 12:00' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:10:08

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '01 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 3' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:49:24', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '1d211df2-882c-4b61-a637-e1eba6ee6854' | System           | 02 Oct 2020 02:50:44 |
| User entered 'Yes (Y)'   | System           | 02 Oct 2020 02:50:44 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:50:06', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '1d211df2-882c-4b61-a637-e1eba6ee6854' | System           | 02 Oct 2020 02:50:44 |
| User entered '98.3'  | System           | 02 Oct 2020 02:50:44 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:50:16', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '1d211df2-882c-4b61-a637-e1eba6ee6854' | System           | 02 Oct 2020 02:50:44 |
| User entered 'Yes (Y)'   | System           | 02 Oct 2020 02:50:44 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 25 Feb 2021 15:55:38 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).          |                                     | 09 Nov 2020 22:01:21 |
| Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'DONE' (Site from System). | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:40:50 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).          | System                              | 02 Oct 2020 02:50:44 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:50:26', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '1d211df2-882c-4b61-a637-e1eba6ee6854'                              | System                              | 02 Oct 2020 02:50:44 |
| User entered '1'  | System                              | 02 Oct 2020 02:50:44 |



US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:10:08

To **PREVENT** pain or fever from occurring

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:50:26', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '1d211df2-882c-4b61-a637-e1eba6ee6854' | System           | 02 Oct 2020 02:50:44 |
| User entered '0'   | System           | 02 Oct 2020 02:50:44 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:50:42', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '1d211df2-882c-4b61-a637-e1eba6ee6854' | System           | 02 Oct 2020 02:50:44 |
| User entered '01 Oct 2020 21:50'   | System           | 02 Oct 2020 02:50:44 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '01 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '02 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 4' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:00:39', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'bfe0f819-ff0e-4325-90f4-17aee5335f28' | System           | 02 Oct 2020 17:01:53 |
| User entered 'Yes (Y)'   | System           | 02 Oct 2020 17:01:53 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:00:53', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'bfe0f819-ff0e-4325-90f4-17aee5335f28' | System           | 02 Oct 2020 17:01:53 |
| User entered '97.8'  | System           | 02 Oct 2020 17:01:53 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:01:02', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'bfe0f819-ff0e-4325-90f4-17aee5335f28' | System           | 02 Oct 2020 17:01:53 |
| User entered 'Yes (Y)'   | System           | 02 Oct 2020 17:01:53 |



US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 25 Feb 2021 15:55:38 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'DONE' (Site from System). | (b) (4), (b) (6)         | 09 Nov 2020 22:01:27 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).   | Marissa Cervenka (b) (4) | 06 Nov 2020 00:41:52 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:01:08', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'bfe0f819-ff0e-4325-90f4-17aee5335f28'   | (b) (4)                  |                      |
| User entered '1'   | System                   | 02 Oct 2020 17:01:53 |
|  | System                   | 02 Oct 2020 17:01:53 |
|  | System                   | 02 Oct 2020 17:01:53 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:10:08

To **PREVENT** pain or fever from occurring

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:01:08', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'bfe0f819-ff0e-4325-90f4-17aee5335f28' | System           | 02 Oct 2020 17:01:53 |
| User entered '0'   | System           | 02 Oct 2020 17:01:53 |

**US3092245**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:01:15', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'bfe0f819-ff0e-4325-90f4-17aee5335f28' | System           | 02 Oct 2020 17:01:53 |
| User entered '02 Oct 2020 12:01'   | System           | 02 Oct 2020 17:01:53 |

**US3092245**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '02 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:10:08

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 5' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:02:11', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b96324e1-00c2-491c-9122-25af7d2b9fff' | System           | 03 Oct 2020 19:02:55 |
| User entered 'Yes (Y)'   | System           | 03 Oct 2020 19:02:55 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:02:28', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b96324e1-00c2-491c-9122-25af7d2b9fff' | System           | 03 Oct 2020 19:02:55 |
| User entered '98.3'  | System           | 03 Oct 2020 19:02:55 |



US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:02:34', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b96324e1-00c2-491c-9122-25af7d2b9fff' | System           | 03 Oct 2020 19:02:55 |
| User entered 'Yes (Y)'   | System           | 03 Oct 2020 19:02:55 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 25 Feb 2021 15:55:38 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'DONE' (Site from System). | (b) (4)                  | 09 Nov 2020 22:01:33 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).   | Marissa Cervenka (b) (4) | 06 Nov 2020 01:35:21 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:02:38', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b96324e1-00c2-491c-9122-25af7d2b9fff'   | (b) (4)                  |                      |
| User entered '1'   | System                   | 03 Oct 2020 19:02:55 |
|  | System                   | 03 Oct 2020 19:02:55 |
|  | System                   | 03 Oct 2020 19:02:55 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:10:08

To **PREVENT** pain or fever from occurring

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:02:38', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b96324e1-00c2-491c-9122-25af7d2b9fff' | System           | 03 Oct 2020 19:02:55 |
| User entered '0'   | System           | 03 Oct 2020 19:02:55 |

**US3092245**

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

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:02:52', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b96324e1-00c2-491c-9122-25af7d2b9fff' | System           | 03 Oct 2020 19:02:55 |
| User entered '03 Oct 2020 14:02'   | System           | 03 Oct 2020 19:02:55 |

**US3092245**

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

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

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

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 6' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:02:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a802f2c1-17c1-4772-b08b-12fe1839d53f' | System           | 04 Oct 2020 17:02:46 |
| User entered 'Yes (Y)'   | System           | 04 Oct 2020 17:02:46 |



US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:02:17', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a802f2c1-17c1-4772-b08b-12fe1839d53f' User entered '98.2' | System           | 04 Oct 2020 17:02:46 |
|  | System           | 04 Oct 2020 17:02:46 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:02:25', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a802f2c1-17c1-4772-b08b-12fe1839d53f' | System           | 04 Oct 2020 17:02:46 |
| User entered 'Yes (Y)'   | System           | 04 Oct 2020 17:02:46 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 25 Feb 2021 15:55:38 |
| User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'DONE' (Site from System). | (b) (4)                  | 09 Nov 2020 22:01:38 |
| User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).   | Marissa Cervenka (b) (4) | 06 Nov 2020 01:37:09 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:02:32', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a802f2c1-17c1-4772-b08b-12fe1839d53f'   | System                   | 04 Oct 2020 17:02:46 |
| User entered '1'   | System                   | 04 Oct 2020 17:02:46 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:10:08

To **PREVENT** pain or fever from occurring

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:02:32', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a802f2c1-17c1-4772-b08b-12fe1839d53f' User entered '0' | System           | 04 Oct 2020 17:02:46 |
|   | System           | 04 Oct 2020 17:02:46 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:02:43', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'a802f2c1-17c1-4772-b08b-12fe1839d53f' | System           | 04 Oct 2020 17:02:46 |
| User entered '04 Oct 2020 12:02'   | System           | 04 Oct 2020 17:02:46 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '05 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 7' | System           | 29 Sep 2020 19:53:45 |



US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:10:08

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '05 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

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

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

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '06 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |



US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 04 Oct 2020 17:02:46 |
| User entered 'Day 8' | System           | 04 Oct 2020 17:02:46 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

Was **TEMPERATURE** taken?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

Please record your **TEMPERATURE** in °F

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

To **PREVENT** pain or fever from occurring

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Temperature\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '06 Oct 2020 12:00' | System           | 04 Oct 2020 17:02:46 |



US3092245

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:10:08

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '07 Oct 2020 11:59' | System           | 04 Oct 2020 17:02:46 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:56:35', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f9560b20-e1a8-445b-b97e-eab0ae18ed87' | System           | 29 Sep 2020 19:57:04 |
| User entered 'None (1)'  | System           | 29 Sep 2020 19:57:04 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:56:39', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f9560b20-e1a8-445b-b97e-eab0ae18ed87' | System           | 29 Sep 2020 19:57:04 |
| User entered 'No (N)'  | System           | 29 Sep 2020 19:57:04 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:56:43', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f9560b20-e1a8-445b-b97e-eab0ae18ed87' | System           | 29 Sep 2020 19:57:04 |
| User entered 'No (N)'  | System           | 29 Sep 2020 19:57:04 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:56:47', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f9560b20-e1a8-445b-b97e-eab0ae18ed87' | System           | 29 Sep 2020 19:57:04 |
| User entered 'None (1)'  | System           | 29 Sep 2020 19:57:04 |

**US3092245**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:56:56', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f9560b20-e1a8-445b-b97e-eab0ae18ed87' | System           | 29 Sep 2020 19:57:04 |
| User entered '29 Sep 2020 14:56'   | System           | 29 Sep 2020 19:57:04 |

**US3092245**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Sep 2020 14:48' | System           | 29 Sep 2020 19:53:45 |



**US3092245**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Sep 2020 17:18' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.                                | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 1, after vaccination (at home)' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:39:35', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'ad1f4d5e-8c32-4741-9e97-1d2f0751f16f' | System           | 30 Sep 2020 03:40:06 |
| User entered 'None (1)'  | System           | 30 Sep 2020 03:40:06 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:39:40', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'ad1f4d5e-8c32-4741-9e97-1d2f0751f16f' | System           | 30 Sep 2020 03:40:06 |
| User entered 'No (N)'  | System           | 30 Sep 2020 03:40:06 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:39:45', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'ad1f4d5e-8c32-4741-9e97-1d2f0751f16f' | System           | 30 Sep 2020 03:40:06 |
| User entered 'No (N)'  | System           | 30 Sep 2020 03:40:06 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:39:51', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'ad1f4d5e-8c32-4741-9e97-1d2f0751f16f' | System           | 30 Sep 2020 03:40:06 |
| User entered 'None (1)'  | System           | 30 Sep 2020 03:40:06 |

**US3092245**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:40:02', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'ad1f4d5e-8c32-4741-9e97-1d2f0751f16f' | System           | 30 Sep 2020 03:40:06 |
| User entered '29 Sep 2020 22:40'   | System           | 30 Sep 2020 03:40:06 |

**US3092245**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Sep 2020 18:13' | System           | 29 Sep 2020 19:53:45 |



**US3092245**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '30 Sep 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 2' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:01:18', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '60ea49f5-5dd1-4e08-b422-9023cc4167da' | System           | 01 Oct 2020 05:01:43 |
| User entered 'None (1)'  | System           | 01 Oct 2020 05:01:43 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:01:22', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '60ea49f5-5dd1-4e08-b422-9023cc4167da' | System           | 01 Oct 2020 05:01:43 |
| User entered 'No (N)'  | System           | 01 Oct 2020 05:01:43 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:01:26', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '60ea49f5-5dd1-4e08-b422-9023cc4167da' | System           | 01 Oct 2020 05:01:43 |
| User entered 'No (N)'  | System           | 01 Oct 2020 05:01:43 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:01:31', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '60ea49f5-5dd1-4e08-b422-9023cc4167da' | System           | 01 Oct 2020 05:01:43 |
| User entered 'None (1)'  | System           | 01 Oct 2020 05:01:43 |

**US3092245**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:01:39', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '60ea49f5-5dd1-4e08-b422-9023cc4167da' | System           | 01 Oct 2020 05:01:43 |
| User entered '01 Oct 2020 00:01'   | System           | 01 Oct 2020 05:01:43 |

**US3092245**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '30 Sep 2020 12:00' | System           | 29 Sep 2020 19:53:45 |



**US3092245**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '01 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 3' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:50:58', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cb9f8ed2-ab07-4061-ad7b-094c04147046' | System           | 02 Oct 2020 02:51:21 |
| User entered 'None (1)'  | System           | 02 Oct 2020 02:51:21 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:10:08

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:50:55', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cb9f8ed2-ab07-4061-ad7b-094c04147046' | System           | 02 Oct 2020 02:51:21 |
| User entered 'No (N)'  | System           | 02 Oct 2020 02:51:21 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:51:03', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cb9f8ed2-ab07-4061-ad7b-094c04147046' | System           | 02 Oct 2020 02:51:21 |
| User entered 'No (N)'  | System           | 02 Oct 2020 02:51:21 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:51:10', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cb9f8ed2-ab07-4061-ad7b-094c04147046' | System           | 02 Oct 2020 02:51:21 |
| User entered 'None (1)'  | System           | 02 Oct 2020 02:51:21 |

**US3092245**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:51:19', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cb9f8ed2-ab07-4061-ad7b-094c04147046' | System           | 02 Oct 2020 02:51:21 |
| User entered '01 Oct 2020 21:51'   | System           | 02 Oct 2020 02:51:21 |

**US3092245**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '01 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |



**US3092245**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '02 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 4' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:01:29', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e9111909-af22-4d10-8751-3e01931c1016' | System           | 02 Oct 2020 17:02:42 |
| User entered 'None (1)'  | System           | 02 Oct 2020 17:02:42 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:10:08

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:01:45', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e9111909-af22-4d10-8751-3e01931c1016' | System           | 02 Oct 2020 17:02:42 |
| User entered 'No (N)'  | System           | 02 Oct 2020 17:02:42 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:01:49', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e9111909-af22-4d10-8751-3e01931c1016' | System           | 02 Oct 2020 17:02:42 |
| User entered 'No (N)'  | System           | 02 Oct 2020 17:02:42 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:01:56', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e9111909-af22-4d10-8751-3e01931c1016' | System           | 02 Oct 2020 17:02:42 |
| User entered 'None (1)'  | System           | 02 Oct 2020 17:02:42 |

**US3092245**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:02:02', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'e9111909-af22-4d10-8751-3e01931c1016' | System           | 02 Oct 2020 17:02:42 |
| User entered '02 Oct 2020 12:02'   | System           | 02 Oct 2020 17:02:42 |

**US3092245**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '02 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |



US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:10:08

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 5' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:03:05', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'be754587-e20a-472c-897f-4d790d438c27' | System           | 03 Oct 2020 19:03:25 |
| User entered 'None (1)'  | System           | 03 Oct 2020 19:03:25 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:10:08

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:03:03', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'be754587-e20a-472c-897f-4d790d438c27' | System           | 03 Oct 2020 19:03:25 |
| User entered 'No (N)'  | System           | 03 Oct 2020 19:03:25 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:03:09', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'be754587-e20a-472c-897f-4d790d438c27' | System           | 03 Oct 2020 19:03:25 |
| User entered 'No (N)'  | System           | 03 Oct 2020 19:03:25 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:03:13', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'be754587-e20a-472c-897f-4d790d438c27' | System           | 03 Oct 2020 19:03:25 |
| User entered 'None (1)'  | System           | 03 Oct 2020 19:03:25 |

**US3092245**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:03:20', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'be754587-e20a-472c-897f-4d790d438c27' | System           | 03 Oct 2020 19:03:25 |
| User entered '03 Oct 2020 14:03'   | System           | 03 Oct 2020 19:03:25 |

**US3092245**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |



**US3092245**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 6' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:02:52', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '5459c978-4cb5-44d1-8a34-ed71c788a4f0' | System           | 04 Oct 2020 17:03:14 |
| User entered 'None (1)'  | System           | 04 Oct 2020 17:03:14 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:10:08

Is there any REDNESS AT INJECTION SITE?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:02:56', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '5459c978-4cb5-44d1-8a34-ed71c788a4f0' | System           | 04 Oct 2020 17:03:14 |
| User entered 'No (N)'  | System           | 04 Oct 2020 17:03:14 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:10:08

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

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:03:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '5459c978-4cb5-44d1-8a34-ed71c788a4f0' | System           | 04 Oct 2020 17:03:14 |
| User entered 'No (N)'  | System           | 04 Oct 2020 17:03:14 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:03:05', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '5459c978-4cb5-44d1-8a34-ed71c788a4f0' | System           | 04 Oct 2020 17:03:14 |
| User entered 'None (1)'  | System           | 04 Oct 2020 17:03:14 |

**US3092245**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:03:12', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '5459c978-4cb5-44d1-8a34-ed71c788a4f0' | System           | 04 Oct 2020 17:03:14 |
| User entered '04 Oct 2020 12:03'   | System           | 04 Oct 2020 17:03:14 |

**US3092245**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |



**US3092245**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '05 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 7' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
|                   |                  |                      |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

Is there any REDNESS AT INJECTION SITE?

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
|                   |                  |                      |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
|                   |                  |                      |

US3092245

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
|                   |                  |                      |



**US3092245**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time Stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '05 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '06 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:55:28', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '27745d84-b0f0-4dc4-9e30-a6e1bbdd9b8f' | System           | 29 Sep 2020 19:56:29 |
| User entered 'None (0)'  | System           | 29 Sep 2020 19:56:29 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:55:31', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '27745d84-b0f0-4dc4-9e30-a6e1bbdd9b8f' | System           | 29 Sep 2020 19:56:29 |
| User entered 'None (0)'  | System           | 29 Sep 2020 19:56:29 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:55:38', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '27745d84-b0f0-4dc4-9e30-a6e1bbdd9b8f' | System           | 29 Sep 2020 19:56:29 |
| User entered 'None (0)'  | System           | 29 Sep 2020 19:56:29 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:55:48', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '27745d84-b0f0-4dc4-9e30-a6e1bbdd9b8f' | System           | 29 Sep 2020 19:56:29 |
| User entered 'No interference with activity (1)'   | System           | 29 Sep 2020 19:56:29 |



**US3092245**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:55:51', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '27745d84-b0f0-4dc4-9e30-a6e1bbdd9b8f' | System           | 29 Sep 2020 19:56:29 |
| User entered 'None (0)'  | System           | 29 Sep 2020 19:56:29 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:55:55', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '27745d84-b0f0-4dc4-9e30-a6e1bbdd9b8f' | System           | 29 Sep 2020 19:56:29 |
| User entered 'None (0)'  | System           | 29 Sep 2020 19:56:29 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:56:05', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '27745d84-b0f0-4dc4-9e30-a6e1bbdd9b8f' | System           | 29 Sep 2020 19:56:29 |
| User entered 'No (N)'  | System           | 29 Sep 2020 19:56:29 |

**US3092245**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T14:56:26', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '27745d84-b0f0-4dc4-9e30-a6e1bbdd9b8f' | System           | 29 Sep 2020 19:56:29 |
| User entered '29 Sep 2020 14:56'   | System           | 29 Sep 2020 19:56:29 |

**US3092245**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Sep 2020 14:48' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Sep 2020 17:18' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                                 | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.                                | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 1, after vaccination (at home)' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:40:08', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cf483a3f-b9d2-4f80-8dce-12bcab59024e' | System           | 30 Sep 2020 03:41:10 |
| User entered 'None (0)'  | System           | 30 Sep 2020 03:41:10 |



US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:40:12', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cf483a3f-b9d2-4f80-8dce-12bcab59024e' | System           | 30 Sep 2020 03:41:10 |
| User entered 'None (0)'  | System           | 30 Sep 2020 03:41:10 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:40:27', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cf483a3f-b9d2-4f80-8dce-12bcab59024e' | System           | 30 Sep 2020 03:41:10 |
| User entered 'No interference with activity (1)'   | System           | 30 Sep 2020 03:41:10 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:40:42', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cf483a3f-b9d2-4f80-8dce-12bcab59024e' | System           | 30 Sep 2020 03:41:10 |
| User entered 'No interference with activity (1)'   | System           | 30 Sep 2020 03:41:10 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:40:46', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cf483a3f-b9d2-4f80-8dce-12bcab59024e' | System           | 30 Sep 2020 03:41:10 |
| User entered 'None (0)'  | System           | 30 Sep 2020 03:41:10 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:40:49', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cf483a3f-b9d2-4f80-8dce-12bcab59024e' | System           | 30 Sep 2020 03:41:10 |
| User entered 'None (0)'  | System           | 30 Sep 2020 03:41:10 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:40:58', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cf483a3f-b9d2-4f80-8dce-12bcab59024e' | System           | 30 Sep 2020 03:41:10 |
| User entered 'No (N)'  | System           | 30 Sep 2020 03:41:10 |

**US3092245**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-09-29T22:41:09', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cf483a3f-b9d2-4f80-8dce-12bcab59024e' | System           | 30 Sep 2020 03:41:10 |
| User entered '29 Sep 2020 22:41'   | System           | 30 Sep 2020 03:41:10 |

**US3092245**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '29 Sep 2020 18:13' | System           | 29 Sep 2020 19:53:45 |



**US3092245**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '30 Sep 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 2' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:01:48', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'eb603030-15ef-4e3d-8358-e6e50fa09774' | System           | 01 Oct 2020 05:03:27 |
| User entered 'None (0)'  | System           | 01 Oct 2020 05:03:27 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:01:52', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'eb603030-15ef-4e3d-8358-e6e50fa09774' | System           | 01 Oct 2020 05:03:27 |
| User entered 'None (0)'  | System           | 01 Oct 2020 05:03:27 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:02:04', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'eb603030-15ef-4e3d-8358-e6e50fa09774' | System           | 01 Oct 2020 05:03:27 |
| User entered 'None (0)'  | System           | 01 Oct 2020 05:03:27 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:02:16', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'eb603030-15ef-4e3d-8358-e6e50fa09774' | System           | 01 Oct 2020 05:03:27 |
| User entered 'No interference with activity (1)'   | System           | 01 Oct 2020 05:03:27 |

**US3092245**

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

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:02:45', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'eb603030-15ef-4e3d-8358-e6e50fa09774' | System           | 01 Oct 2020 05:03:27 |
| User entered 'None (0)'  | System           | 01 Oct 2020 05:03:27 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:02:49', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'eb603030-15ef-4e3d-8358-e6e50fa09774' | System           | 01 Oct 2020 05:03:27 |
| User entered 'None (0)'  | System           | 01 Oct 2020 05:03:27 |



US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:02:56', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'eb603030-15ef-4e3d-8358-e6e50fa09774' | System           | 01 Oct 2020 05:03:27 |
| User entered 'No (N)'  | System           | 01 Oct 2020 05:03:27 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:10:08

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T00:03:24', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'eb603030-15ef-4e3d-8358-e6e50fa09774' | System           | 01 Oct 2020 05:03:27 |
| User entered '01 Oct 2020 00:03'   | System           | 01 Oct 2020 05:03:27 |

**US3092245**

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

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '30 Sep 2020 12:00' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

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

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '01 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 3' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:10:08**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:51:28', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '83903f08-b90c-44fe-a603-5f9ad8781d5a' | System           | 02 Oct 2020 02:52:22 |
| User entered 'None (0)'  | System           | 02 Oct 2020 02:52:22 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:10:08**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:51:42', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '83903f08-b90c-44fe-a603-5f9ad8781d5a' | System           | 02 Oct 2020 02:52:22 |
| User entered 'No interference with activity (1)'   | System           | 02 Oct 2020 02:52:22 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:51:48', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '83903f08-b90c-44fe-a603-5f9ad8781d5a' | System           | 02 Oct 2020 02:52:22 |
| User entered 'No interference with activity (1)'   | System           | 02 Oct 2020 02:52:22 |



US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:51:56', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '83903f08-b90c-44fe-a603-5f9ad8781d5a' | System           | 02 Oct 2020 02:52:22 |
| User entered 'No interference with activity (1)'   | System           | 02 Oct 2020 02:52:22 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:10:08**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:52:01', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '83903f08-b90c-44fe-a603-5f9ad8781d5a' | System           | 02 Oct 2020 02:52:22 |
| User entered 'No interference with activity or 1-2 episodes/24 hours (1)'  | System           | 02 Oct 2020 02:52:22 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:52:06', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '83903f08-b90c-44fe-a603-5f9ad8781d5a' | System           | 02 Oct 2020 02:52:22 |
| User entered 'None (0)'  | System           | 02 Oct 2020 02:52:22 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:52:10', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '83903f08-b90c-44fe-a603-5f9ad8781d5a' | System           | 02 Oct 2020 02:52:22 |
| User entered 'No (N)'  | System           | 02 Oct 2020 02:52:22 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:10:08

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-01T21:52:20', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '83903f08-b90c-44fe-a603-5f9ad8781d5a' | System           | 02 Oct 2020 02:52:22 |
| User entered '01 Oct 2020 21:52'   | System           | 02 Oct 2020 02:52:22 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '01 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '02 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 4' | System           | 29 Sep 2020 19:53:45 |



US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:02:08', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f3727bde-d528-418e-90bd-a2502ac08ea0' | System           | 02 Oct 2020 17:03:08 |
| User entered 'None (0)'  | System           | 02 Oct 2020 17:03:08 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:02:14', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f3727bde-d528-418e-90bd-a2502ac08ea0' | System           | 02 Oct 2020 17:03:08 |
| User entered 'None (0)'  | System           | 02 Oct 2020 17:03:08 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:02:19', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f3727bde-d528-418e-90bd-a2502ac08ea0' | System           | 02 Oct 2020 17:03:08 |
| User entered 'No interference with activity (1)'   | System           | 02 Oct 2020 17:03:08 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:02:24', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f3727bde-d528-418e-90bd-a2502ac08ea0' | System           | 02 Oct 2020 17:03:08 |
| User entered 'No interference with activity (1)'   | System           | 02 Oct 2020 17:03:08 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:02:29', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f3727bde-d528-418e-90bd-a2502ac08ea0' | System           | 02 Oct 2020 17:03:08 |
| User entered 'None (0)'  | System           | 02 Oct 2020 17:03:08 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:02:32', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f3727bde-d528-418e-90bd-a2502ac08ea0' | System           | 02 Oct 2020 17:03:08 |
| User entered 'None (0)'  | System           | 02 Oct 2020 17:03:08 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:02:37', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f3727bde-d528-418e-90bd-a2502ac08ea0' | System           | 02 Oct 2020 17:03:08 |
| User entered 'No (N)'  | System           | 02 Oct 2020 17:03:08 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:10:08

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-02T12:02:43', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f3727bde-d528-418e-90bd-a2502ac08ea0' | System           | 02 Oct 2020 17:03:08 |
| User entered '02 Oct 2020 12:02'   | System           | 02 Oct 2020 17:03:08 |



**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '02 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 5' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:03:29', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '04b1c456-5dd2-4bec-be39-d10dd181f3fe' | System           | 03 Oct 2020 19:04:09 |
| User entered 'None (0)'  | System           | 03 Oct 2020 19:04:09 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:03:33', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '04b1c456-5dd2-4bec-be39-d10dd181f3fe' | System           | 03 Oct 2020 19:04:09 |
| User entered 'None (0)'  | System           | 03 Oct 2020 19:04:09 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:03:39', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '04b1c456-5dd2-4bec-be39-d10dd181f3fe' | System           | 03 Oct 2020 19:04:09 |
| User entered 'No interference with activity (1)'   | System           | 03 Oct 2020 19:04:09 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:03:47', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '04b1c456-5dd2-4bec-be39-d10dd181f3fe' | System           | 03 Oct 2020 19:04:09 |
| User entered 'No interference with activity (1)'   | System           | 03 Oct 2020 19:04:09 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:03:51', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '04b1c456-5dd2-4bec-be39-d10dd181f3fe' | System           | 03 Oct 2020 19:04:09 |
| User entered 'None (0)'  | System           | 03 Oct 2020 19:04:09 |



**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:03:54', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '04b1c456-5dd2-4bec-be39-d10dd181f3fe' | System           | 03 Oct 2020 19:04:09 |
| User entered 'None (0)'  | System           | 03 Oct 2020 19:04:09 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:03:58', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '04b1c456-5dd2-4bec-be39-d10dd181f3fe' | System           | 03 Oct 2020 19:04:09 |
| User entered 'No (N)'  | System           | 03 Oct 2020 19:04:09 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-03T14:04:05', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '04b1c456-5dd2-4bec-be39-d10dd181f3fe' | System           | 03 Oct 2020 19:04:09 |
| User entered '03 Oct 2020 14:04'   | System           | 03 Oct 2020 19:04:09 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '03 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 6' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:10:08**

**HEADACHE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:03:19', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37dd9000-2041-4d07-8dc0-a5ff74768e7b' | System           | 04 Oct 2020 17:03:59 |
| User entered 'None (0)'  | System           | 04 Oct 2020 17:03:59 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:10:08**

**FATIGUE**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:03:22', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37dd9000-2041-4d07-8dc0-a5ff74768e7b' | System           | 04 Oct 2020 17:03:59 |
| User entered 'None (0)'  | System           | 04 Oct 2020 17:03:59 |



US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:03:29', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37dd9000-2041-4d07-8dc0-a5ff74768e7b' | System           | 04 Oct 2020 17:03:59 |
| User entered 'No interference with activity (1)'   | System           | 04 Oct 2020 17:03:59 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:03:37', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37dd9000-2041-4d07-8dc0-a5ff74768e7b' | System           | 04 Oct 2020 17:03:59 |
| User entered 'No interference with activity (1)'   | System           | 04 Oct 2020 17:03:59 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:10:08**

**NAUSEA/VOMITING**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:03:42', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37dd9000-2041-4d07-8dc0-a5ff74768e7b' | System           | 04 Oct 2020 17:03:59 |
| User entered 'None (0)'  | System           | 04 Oct 2020 17:03:59 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

**CHILLS**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:03:45', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37dd9000-2041-4d07-8dc0-a5ff74768e7b' | System           | 04 Oct 2020 17:03:59 |
| User entered 'None (0)'  | System           | 04 Oct 2020 17:03:59 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:03:49', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37dd9000-2041-4d07-8dc0-a5ff74768e7b' | System           | 04 Oct 2020 17:03:59 |
| User entered 'No (N)'  | System           | 04 Oct 2020 17:03:59 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-10-04T12:03:56', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '37dd9000-2041-4d07-8dc0-a5ff74768e7b' | System           | 04 Oct 2020 17:03:59 |
| User entered '04 Oct 2020 12:03'   | System           | 04 Oct 2020 17:03:59 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '04 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '05 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |



**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 29 Sep 2020 19:53:45 |
| User entered 'Day 7' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:10:08**

**HEADACHE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**FATIGUE**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

**NAUSEA/VOMITING**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:10:08**

**CHILLS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |



US3092245

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:10:08

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
|                   |                  |                      |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '05 Oct 2020 12:00' | System           | 29 Sep 2020 19:53:45 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '06 Oct 2020 11:59' | System           | 29 Sep 2020 19:53:45 |

US3092245

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 04 Oct 2020 17:03:59 |
| User entered 'Day 8' | System           | 04 Oct 2020 17:03:59 |

US3092245

Folder: Diary Dose 2 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 15:10:08

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '06 Oct 2020 12:00' | System           | 04 Oct 2020 17:03:59 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '07 Oct 2020 11:59' | System           | 04 Oct 2020 17:03:59 |



US3092245

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 15:10:08

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 04 Oct 2020 17:03:59 |
| User entered 'Day 8' | System           | 04 Oct 2020 17:03:59 |

US3092245

Folder: Diary Dose 2 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 15:10:08

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '06 Oct 2020 12:00' | System           | 04 Oct 2020 17:03:59 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '07 Oct 2020 11:59' | System           | 04 Oct 2020 17:03:59 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| Data entry locked.   | System           | 04 Oct 2020 17:02:46 |
| User entered 'Day 8' | System           | 04 Oct 2020 17:02:46 |

US3092245

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:10:08

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 15:55:38 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Time stamp](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |



**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Open Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '06 Oct 2020 12:00' | System           | 04 Oct 2020 17:02:46 |

**US3092245**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:10:08**

[PC Close Date & Time](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 25 Feb 2021 15:55:38 |
| User entered '07 Oct 2020 11:59' | System           | 04 Oct 2020 17:02:46 |

**US3092245**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Was Contact Attempted?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 06 Oct 2020 17:46:08 |

**US3092245**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '6 Oct 2020' | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 06 Oct 2020 17:46:08 |

US3092245

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:08

[Please select one status for the follow-up contact](#)

| Audit                                      | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded.                  | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>destiny robinson (b) (4) | 06 Oct 2020 17:46:08 |

**US3092245**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 06 Oct 2020 17:46:08 |

US3092245

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:08

[Is the participant continuing to the next visit?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>destiny robinson (b) (4) | 06 Oct 2020 17:46:14 |

**US3092245**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'I'  | System           | 06 Oct 2020 17:46:14 |



**US3092245**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Was Contact Attempted?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 13 Oct 2020 20:04:07 |

**US3092245**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--|----------------------|
| Data hard locked.          | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '13 Oct 2020' | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 13 Oct 2020 20:04:07 |

**US3092245**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Please select one status for the follow-up contact](#)

| Audit                                      | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded.                  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 13 Oct 2020 20:04:07 |

**US3092245**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 13 Oct 2020 20:04:07 |

US3092245

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:08

[Is the participant continuing to the next visit?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 13 Oct 2020 20:04:10 |

**US3092245**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'I'  | System           | 13 Oct 2020 20:04:10 |

**US3092245**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Was Contact Attempted?](#)

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 21 Oct 2020 13:33:43 |

**US3092245**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)         | 03 Apr 2021 23:19:38 |
| User signature succeeded.                                      | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '20 Oct 2020' reason for change: Data Entry Error | (b) (4)                  |                      |
|  | destiny robinson (b) (4) | 21 Oct 2020 13:33:48 |
| User entered '21 Oct 2020'                                     | (b) (4)                  |                      |
|  | destiny robinson (b) (4) | 21 Oct 2020 13:33:43 |
|  | (b) (4)                  |                      |



**US3092245**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Please select one status for the follow-up contact](#)

| Audit                                      | User   | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded.                  | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 21 Oct 2020 13:33:43 |

US3092245

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:10:08

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User   | Time (GMT)           |
|---------------------------|--|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                               | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>destiny robinson (b) (4)<br>(b) (4) | 21 Oct 2020 13:33:43 |

US3092245

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:08

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 21 Oct 2020 12:03:54 |

**US3092245**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'I'  | System           | 21 Oct 2020 12:03:54 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Was this visit performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 21 Oct 2020 12:04:08 |

US3092245

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:08

Visit date (dd MMM yyyy)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                    | 03 Apr 2021 23:19:45 |
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:48 |
| User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).                     | (b) (4)<br>(b) (4), (b) (6)         | 09 Nov 2020 22:01:52 |
| Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'DEVIATION NOTED' (Site from System). | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 01:36:02 |
| User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).                     | System                              | 21 Oct 2020 12:04:08 |
| User entered '20 Oct 2020'  | Catina Adams (b) (4)<br>(b) (4)     | 21 Oct 2020 12:04:08 |

US3092245

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:08

[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 23:19:45 |
| User signature succeeded.      | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Clinic (Clinic)' | Catina Adams (b) (4)   | 21 Oct 2020 12:04:08 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Folder OID](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| Data hard locked.     | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'VISIT3' | System           | 21 Oct 2020 12:04:08 |



**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Were vital signs assessed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 21 Oct 2020 12:06:06 |

US3092245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '20 Oct 2020' | Catina Adams (b) (4)   | 21 Oct 2020 12:06:06 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

**Time of assessment (00:00-23:59)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '13:30'      | Catina Adams (b) (4)   | 21 Oct 2020 12:06:06 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered '20 Oct 2020 13:30' | System           | 21 Oct 2020 12:06:06 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

**Temperature (xxx.x)**

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '98.2' F     | Catina Adams (b) (4)   | 21 Oct 2020 12:06:06 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Route of measurement](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Oral (Oral)' | Catina Adams (b) (4)   | 21 Oct 2020 12:06:06 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[If Other, specify](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered empty.       | Catina Adams (b) (4)   | 21 Oct 2020 12:06:06 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '80'         | Catina Adams (b) (4)   | 21 Oct 2020 12:06:06 |



**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'bpm' | System           | 21 Oct 2020 12:06:06 |

US3092245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '15'         | Catina Adams (b) (4)   | 21 Oct 2020 12:06:06 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'breaths/min' | System           | 21 Oct 2020 12:06:06 |

US3092245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

Systolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '160'        | Catina Adams (b) (4)   | 21 Oct 2020 12:06:06 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'mmHg' | System           | 21 Oct 2020 12:06:06 |

US3092245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

Diastolic Blood Pressure (xxx)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '67'         | Catina Adams (b) (4)   | 21 Oct 2020 12:06:06 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'mmHg' | System           | 21 Oct 2020 12:06:06 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Height \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
|                   |                  |                      |



US3092245

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

Weight (derived)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
|                   |                  |                      |

US3092245

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:08

[Was the physical examination performed?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 21 Oct 2020 12:04:22 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:10:08**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '20 Oct 2020' | Catina Adams (b) (4)   | 21 Oct 2020 12:04:22 |

US3092245

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:08

[Was the sample collected?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 21 Oct 2020 12:04:53 |

US3092245

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:08

Collection date (*dd MMM yyyy*)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '20 Oct 2020' | Catina Adams (b) (4)   | 21 Oct 2020 12:04:53 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered '14:00'      | Catina Adams (b) (4)   | 21 Oct 2020 12:04:53 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

[Collection date and time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered '20 Oct 2020 14:00' | System           | 21 Oct 2020 12:04:53 |

**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 03 Apr 2021 23:19:45 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:48 |
| User entered 'Yes (Y)'    | Catina Adams (b) (4)   | 21 Oct 2020 12:04:30 |



**US3092245**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 23:19:45 |
| User entered 'I'  | System           | 21 Oct 2020 12:04:30 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |
| Data entry locked.                        | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 64'                     | System           | 27 Aug 2020 18:57:14 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

US3092245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Chills](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Cough](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Shortness of breath](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Difficulty breathing](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Fatigue](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Muscle aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Body aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Headache](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[New loss of taste](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[New loss of smell](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Sore throat](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Congestion](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Runny nose](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Nausea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Vomiting](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Diarrhea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |



US3092245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |
| Data entry locked.                        | System           | 27 Aug 2020 18:57:14 |
| User entered '27 Oct 2020 00:01'          | System           | 27 Aug 2020 18:57:14 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |
| Data entry locked.                        | System           | 27 Aug 2020 18:57:14 |
| User entered '31 Oct 2020 23:59'          | System           | 27 Aug 2020 18:57:14 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |
| Data entry locked.                        | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 71'                     | System           | 27 Aug 2020 18:57:14 |

US3092245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

US3092245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

US3092245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

Fever (Temperature  $\geq$  100.4°F/38°C)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Chills](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Cough](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

US3092245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

[Shortness of breath](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Difficulty breathing](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Fatigue](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Muscle aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Body aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Headache](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[New loss of taste](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[New loss of smell](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Sore throat](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Congestion](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Runny nose](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |



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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Nausea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Vomiting](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Diarrhea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
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US3092245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |
| Data entry locked.                        | System           | 27 Aug 2020 18:57:14 |
| User entered '03 Nov 2020 00:01'          | System           | 27 Aug 2020 18:57:14 |



**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |
| Data entry locked.                        | System           | 27 Aug 2020 18:57:14 |
| User entered '07 Nov 2020 23:59'          | System           | 27 Aug 2020 18:57:14 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |
| Data entry locked.                        | System           | 27 Aug 2020 18:57:14 |
| User entered 'Day 78'                     | System           | 27 Aug 2020 18:57:14 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

US3092245

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
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**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
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**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Chills](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Cough](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Shortness of breath](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Difficulty breathing](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Fatigue](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Muscle aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Body aches](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Headache](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[New loss of taste](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[New loss of smell](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Sore throat](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Congestion](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Runny nose](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Nausea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Vomiting](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Diarrhea](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |
| Data entry locked.                        | System           | 27 Aug 2020 18:57:14 |
| User entered '10 Nov 2020 00:01'          | System           | 27 Aug 2020 18:57:14 |

**US3092245**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit                                     | User             | Time (GMT)           |
|---|------------------|----------------------|
| Data hard locked.                         | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| DataPoint activated (WR#5335027)          | System           | 01 Apr 2021 17:41:56 |
| Amendment Manager: DataPoint Inactivated. | System           | 19 Nov 2020 19:19:23 |
| Data entry locked.                        | System           | 27 Aug 2020 18:57:14 |
| User entered '14 Nov 2020 23:59'          | System           | 27 Aug 2020 18:57:14 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 89' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2020-11-24T11:09:53', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f9a18d6c-2d59-44ad-abb3-aebfed1dd15f' | System | 24 Nov 2020 17:11:27 |
| User entered 'Yes (Y)'   | System | 24 Nov 2020 17:11:27 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2020-11-24T11:10:05', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f9a18d6c-2d59-44ad-abb3-aebfed1dd15f' | System | 24 Nov 2020 17:11:27 |
| User entered 'No (N)'  | System | 24 Nov 2020 17:11:27 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-11-24T11:10:22', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f9a18d6c-2d59-44ad-abb3-aebfed1dd15f' | System | 24 Nov 2020 17:11:27 |
| User entered 'No (N)'  | System | 24 Nov 2020 17:11:27 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-11-24T11:10:34', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f9a18d6c-2d59-44ad-abb3-aebfed1dd15f' | System | 24 Nov 2020 17:11:27 |
| User entered 'Yes (Y)'   | System | 24 Nov 2020 17:11:27 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-11-24T11:10:48', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f9a18d6c-2d59-44ad-abb3-aebfed1dd15f' | System | 24 Nov 2020 17:11:27 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 24 Nov 2020 17:11:27 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-11-24T11:11:18', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f9a18d6c-2d59-44ad-abb3-aebfed1dd15f' | System | 24 Nov 2020 17:11:27 |
| User entered '24 Nov 2020 11:11:18'  | System | 24 Nov 2020 17:11:27 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '21 Nov 2020 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '25 Nov 2020 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                    | User   | Time (GMT)           |
|--|--------|----------------------|
| Amendment Manager: Data entry locked.    | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 96' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '28 Nov 2020 00:01' | System | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '02 Dec 2020 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 19:19:23 |

US3092245

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:10:08

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)           |
|---|--------------------------|----------------------|
| User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).  | (b) (4), (b) (6)         | 16 Mar 2021 20:12:39 |
| Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Subject saw healthcare provider to f/u with AE #1. This has been previously reported. ' (Site from DM). | Marissa Cervenka (b) (4) | 02 Mar 2021 17:03:34 |
| User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).  | (b) (4), (b) (6)         | 26 Feb 2021 10:07:38 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-12-07T09:49:50', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6622ed1d-e87b-42a8-95a3-b3d34d319c0a'  | System                   | 07 Dec 2020 15:51:33 |
| User entered 'Yes (Y)'  | System                   | 07 Dec 2020 15:51:33 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2020-12-07T09:49:59', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6622ed1d-e87b-42a8-95a3-b3d34d319c0a' | System | 07 Dec 2020 15:51:33 |
| User entered 'No (N)'  | System | 07 Dec 2020 15:51:33 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-12-07T09:50:05', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6622ed1d-e87b-42a8-95a3-b3d34d319c0a' | System | 07 Dec 2020 15:51:33 |
| User entered 'No (N)'  | System | 07 Dec 2020 15:51:33 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-12-07T09:50:15', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6622ed1d-e87b-42a8-95a3-b3d34d319c0a' | System | 07 Dec 2020 15:51:33 |
| User entered 'Yes (Y)'   | System | 07 Dec 2020 15:51:33 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-12-07T09:50:40', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6622ed1d-e87b-42a8-95a3-b3d34d319c0a' | System | 07 Dec 2020 15:51:33 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 07 Dec 2020 15:51:33 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-12-07T09:51:19', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '6622ed1d-e87b-42a8-95a3-b3d34d319c0a' | System | 07 Dec 2020 15:51:33 |
| User entered '07 Dec 2020 09:51:19'  | System | 07 Dec 2020 15:51:33 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '05 Dec 2020 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '09 Dec 2020 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2020-12-12T14:09:16', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '41ebc78d-1c11-4c72-8117-cef9546d5b33' | System | 12 Dec 2020 20:10:05 |
| User entered 'No (N)'  | System | 12 Dec 2020 20:10:05 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2020-12-12T14:09:42', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '41ebc78d-1c11-4c72-8117-cef9546d5b33' | System | 12 Dec 2020 20:10:05 |
| User entered 'No (N)'  | System | 12 Dec 2020 20:10:05 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-12-12T14:10:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '41ebc78d-1c11-4c72-8117-cef9546d5b33' | System | 12 Dec 2020 20:10:05 |
| User entered '12 Dec 2020 14:10:00'  | System | 12 Dec 2020 20:10:05 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '12 Dec 2020 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '16 Dec 2020 23:59' | System | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2020-12-23T12:08:40', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b090b3d0-d62c-4f66-ad38-344215432f23' | System | 23 Dec 2020 18:09:10 |
| User entered 'No (N)'  | System | 23 Dec 2020 18:09:10 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2020-12-23T12:08:49', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b090b3d0-d62c-4f66-ad38-344215432f23' | System | 23 Dec 2020 18:09:10 |
| User entered 'No (N)'  | System | 23 Dec 2020 18:09:10 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-12-23T12:09:05', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b090b3d0-d62c-4f66-ad38-344215432f23' | System | 23 Dec 2020 18:09:10 |
| User entered '23 Dec 2020 12:09:05'  | System | 23 Dec 2020 18:09:10 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '19 Dec 2020 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '23 Dec 2020 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2020-12-28T12:01:01', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '3a138d65-aba6-473a-8e3a-e67110a891d9' | System | 28 Dec 2020 18:01:34 |
| User entered 'No (N)'  | System | 28 Dec 2020 18:01:34 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2020-12-28T12:01:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '3a138d65-aba6-473a-8e3a-e67110a891d9' | System | 28 Dec 2020 18:01:34 |
| User entered 'No (N)'  | System | 28 Dec 2020 18:01:34 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2020-12-28T12:01:25', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '3a138d65-aba6-473a-8e3a-e67110a891d9' User entered '28 Dec 2020 12:01:25' | System | 28 Dec 2020 18:01:34 |
|  | System | 28 Dec 2020 18:01:34 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '26 Dec 2020 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '30 Dec 2020 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-01-04T18:09:46', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered 'Yes (Y)'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-01-04T18:09:54', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered 'No (N)'  | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:11:26', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered 'Yes (Y)'   | System | 05 Jan 2021 00:13:09 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' User entered '0' | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Chills](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Cough](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '1'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Shortness of breath](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Difficulty breathing](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Fatigue](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Muscle aches](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Body aches](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Headache](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[New loss of taste](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[New loss of smell](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Sore throat](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Congestion](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Runny nose](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Nausea](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Vomiting](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Diarrhea](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:07', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '0'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:13', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:10:18', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered 'Yes (Y)'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:10:44', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-04T18:12:56', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'f84f82dd-c034-4b65-8e1c-5b20e937398f' | System | 05 Jan 2021 00:13:09 |
| User entered '04 Jan 2021 18:12:56'  | System | 05 Jan 2021 00:13:09 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '02 Jan 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '06 Jan 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-01-09T12:53:55', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'afe8f2c5-9d08-4301-bf61-abce44a09a3f' | System | 09 Jan 2021 18:54:21 |
| User entered 'No (N)'  | System | 09 Jan 2021 18:54:21 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-01-09T12:54:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'afe8f2c5-9d08-4301-bf61-abce44a09a3f' | System | 09 Jan 2021 18:54:21 |
| User entered 'No (N)'  | System | 09 Jan 2021 18:54:21 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-09T12:54:15', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'afe8f2c5-9d08-4301-bf61-abce44a09a3f' User entered '09 Jan 2021 12:54:15' | System | 09 Jan 2021 18:54:21 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '09 Jan 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '13 Jan 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '16 Jan 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '20 Jan 2021 23:59' | System | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-01-23T08:36:09', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '39992110-cf4d-435e-a288-08240bd94361' | System | 23 Jan 2021 14:36:36 |
| User entered 'No (N)'  | System | 23 Jan 2021 14:36:36 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-01-23T08:36:18', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '39992110-cf4d-435e-a288-08240bd94361' | System | 23 Jan 2021 14:36:36 |
| User entered 'No (N)'  | System | 23 Jan 2021 14:36:36 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-01-23T08:36:30', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '39992110-cf4d-435e-a288-08240bd94361' User entered '23 Jan 2021 08:36:30' | System | 23 Jan 2021 14:36:36 |
|  | System | 23 Jan 2021 14:36:36 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '23 Jan 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '27 Jan 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-02-03T11:41:46', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8fd58af6-6b86-469c-bc0e-fcd4a7556ca4' | System | 03 Feb 2021 17:42:16 |
| User entered 'No (N)'  | System | 03 Feb 2021 17:42:16 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-02-03T11:41:58', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8fd58af6-6b86-469c-bc0e-fcd4a7556ca4' | System | 03 Feb 2021 17:42:16 |
| User entered 'No (N)'  | System | 03 Feb 2021 17:42:16 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-02-03T11:42:11', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '8fd58af6-6b86-469c-bc0e-fcd4a7556ca4' | System | 03 Feb 2021 17:42:16 |
| User entered '03 Feb 2021 11:42:11'  | System | 03 Feb 2021 17:42:16 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '30 Jan 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '03 Feb 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-02-06T22:12:41', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cd935e66-da2f-4635-b6ca-c5ea58974396' | System | 07 Feb 2021 04:13:08 |
| User entered 'No (N)'  | System | 07 Feb 2021 04:13:08 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-02-06T22:12:47', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cd935e66-da2f-4635-b6ca-c5ea58974396' | System | 07 Feb 2021 04:13:08 |
| User entered 'No (N)'  | System | 07 Feb 2021 04:13:08 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-02-06T22:13:05', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cd935e66-da2f-4635-b6ca-c5ea58974396' | System | 07 Feb 2021 04:13:08 |
| User entered '06 Feb 2021 22:13:05'  | System | 07 Feb 2021 04:13:08 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '06 Feb 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '10 Feb 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-02-13T08:57:05', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '694961d3-7b9d-452f-9563-041bebeb309a' | System | 13 Feb 2021 14:57:31 |
| User entered 'No (N)'  | System | 13 Feb 2021 14:57:31 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-02-13T08:57:12', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '694961d3-7b9d-452f-9563-041bebeb309a' | System | 13 Feb 2021 14:57:31 |
| User entered 'No (N)'  | System | 13 Feb 2021 14:57:31 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-02-13T08:57:25', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '694961d3-7b9d-452f-9563-041bebeb309a' | System | 13 Feb 2021 14:57:31 |
| User entered '13 Feb 2021 08:57:25'  | System | 13 Feb 2021 14:57:31 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '13 Feb 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '17 Feb 2021 23:59' | System | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-02-23T19:23:26-06:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b684f110-dc6b-458f-a3e2-5b2fe4522273' | System | 24 Feb 2021 01:23:49 |
| User entered 'No (N)'  | System | 24 Feb 2021 01:23:49 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-02-23T19:23:34-06:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b684f110-dc6b-458f-a3e2-5b2fe4522273' User entered 'No (N)' | System | 24 Feb 2021 01:23:49 |
|  | System | 24 Feb 2021 01:23:49 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-02-23T19:23:43-06:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'b684f110-dc6b-458f-a3e2-5b2fe4522273' User entered '23 Feb 2021 19:23:43' | System | 24 Feb 2021 01:23:49 |
|  | System | 24 Feb 2021 01:23:49 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '20 Feb 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '24 Feb 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-03-02T22:28:59-06:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '5977af32-1959-45be-ad28-842aa425c635' | System | 03 Mar 2021 04:29:22 |
| User entered 'No (N)'  | System | 03 Mar 2021 04:29:22 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-03-02T22:29:04-06:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '5977af32-1959-45be-ad28-842aa425c635' | System | 03 Mar 2021 04:29:22 |
| User entered 'No (N)'  | System | 03 Mar 2021 04:29:22 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-03-02T22:29:16-06:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '5977af32-1959-45be-ad28-842aa425c635' | System | 03 Mar 2021 04:29:22 |
| User entered '02 Mar 2021 22:29:16'  | System | 03 Mar 2021 04:29:22 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '27 Feb 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '03 Mar 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-03-09T09:24:44-06:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '53d1ee68-1f1f-4d01-bad6-e7e07ca9c3d6' | System | 09 Mar 2021 15:25:06 |
| User entered 'No (N)'  | System | 09 Mar 2021 15:25:06 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-03-09T09:24:52-06:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '53d1ee68-1f1f-4d01-bad6-e7e07ca9c3d6' | System | 09 Mar 2021 15:25:06 |
| User entered 'No (N)'  | System | 09 Mar 2021 15:25:06 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-03-09T09:24:58-06:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '53d1ee68-1f1f-4d01-bad6-e7e07ca9c3d6' User entered '09 Mar 2021 09:24:58' | System | 09 Mar 2021 15:25:06 |
|  | System | 09 Mar 2021 15:25:06 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '06 Mar 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '10 Mar 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-03-15T15:40:51-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '2b665738-d1df-4f4e-8cbe-e734ff6273fa' User entered 'No (N)' | System | 15 Mar 2021 20:41:14 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-03-15T15:40:56-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '2b665738-d1df-4f4e-8cbe-e734ff6273fa' User entered 'No (N)' | System | 15 Mar 2021 20:41:14 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-03-15T15:41:08-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '2b665738-d1df-4f4e-8cbe-e734ff6273fa' User entered '15 Mar 2021 15:41:08' | System | 15 Mar 2021 20:41:14 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '13 Mar 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '17 Mar 2021 23:59' | System | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-03-24T11:44:47-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '3e4b77e8-b0b8-404f-81d7-de0719381c6b' | System | 24 Mar 2021 16:45:23 |
| User entered 'No (N)'  | System | 24 Mar 2021 16:45:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-03-24T11:44:53-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '3e4b77e8-b0b8-404f-81d7-de0719381c6b' | System | 24 Mar 2021 16:45:23 |
| User entered 'No (N)'  | System | 24 Mar 2021 16:45:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-03-24T11:45:16-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '3e4b77e8-b0b8-404f-81d7-de0719381c6b' User entered '24 Mar 2021 11:45:16' | System | 24 Mar 2021 16:45:23 |
|  | System | 24 Mar 2021 16:45:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '20 Mar 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '24 Mar 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-03-29T12:02:45-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '64e999ab-4afe-4c02-9f27-61b0ec16d996' | System | 29 Mar 2021 17:05:39 |
| User entered 'No (N)'  | System | 29 Mar 2021 17:05:39 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-03-29T12:02:49-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '64e999ab-4afe-4c02-9f27-61b0ec16d996' | System | 29 Mar 2021 17:05:39 |
| User entered 'No (N)'  | System | 29 Mar 2021 17:05:39 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-03-29T12:02:56-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '64e999ab-4afe-4c02-9f27-61b0ec16d996' User entered '29 Mar 2021 12:02:56' | System | 29 Mar 2021 17:05:39 |
|  | System | 29 Mar 2021 17:05:39 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '27 Mar 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '31 Mar 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-04-03T00:02:29-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '865d43a6-b0da-461f-9e58-0a7cdc3b0951' User entered 'No (N)' | System | 03 Apr 2021 05:03:21 |
|  | System | 03 Apr 2021 05:03:21 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-04-03T00:02:34-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '865d43a6-b0da-461f-9e58-0a7cdc3b0951' User entered 'No (N)' | System | 03 Apr 2021 05:03:21 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-04-03T00:02:41-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '865d43a6-b0da-461f-9e58-0a7cdc3b0951' User entered '03 Apr 2021 00:02:41' | System | 03 Apr 2021 05:03:21 |
|  | System | 03 Apr 2021 05:03:21 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '03 Apr 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '07 Apr 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-04-13T20:11:49-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cb16dc10-91db-42b5-bc4e-3b8635a0d41e' | System | 14 Apr 2021 01:13:58 |
| User entered 'No (N)'  | System | 14 Apr 2021 01:13:58 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-04-13T20:11:23-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cb16dc10-91db-42b5-bc4e-3b8635a0d41e' | System | 14 Apr 2021 01:13:58 |
| User entered 'No (N)'  | System | 14 Apr 2021 01:13:58 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-04-13T20:12:04-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'cb16dc10-91db-42b5-bc4e-3b8635a0d41e' User entered '13 Apr 2021 20:12:04' | System | 14 Apr 2021 01:13:58 |
|  | System | 14 Apr 2021 01:13:58 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '10 Apr 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '14 Apr 2021 23:59' | System | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-04-19T12:01:23-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'bfc4cc28-53ab-4ec9-8dc9-6ef0b3927538' | System | 19 Apr 2021 17:04:29 |
| User entered 'No (N)'  | System | 19 Apr 2021 17:04:29 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-04-19T12:02:07-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'bfc4cc28-53ab-4ec9-8dc9-6ef0b3927538' | System | 19 Apr 2021 17:04:29 |
| User entered 'No (N)'  | System | 19 Apr 2021 17:04:29 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-04-19T12:02:12-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'bfc4cc28-53ab-4ec9-8dc9-6ef0b3927538' | System | 19 Apr 2021 17:04:29 |
| User entered '19 Apr 2021 12:02:12'  | System | 19 Apr 2021 17:04:29 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '17 Apr 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '21 Apr 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[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 (a4f05205e0ef3285)', Time: '2021-04-28T10:45:08-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'aea02689-460d-420b-afce-5ed150da8404' | System | 28 Apr 2021 23:04:11 |
| User entered 'Yes (Y)'   | System | 28 Apr 2021 23:04:11 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you been exposed to someone with 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 (a4f05205e0ef3285)', Time: '2021-04-28T10:45:20-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'aea02689-460d-420b-afce-5ed150da8404' | System | 28 Apr 2021 23:04:11 |
| User entered 'No (N)'  | System | 28 Apr 2021 23:04:11 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-04-28T10:45:27-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'aea02689-460d-420b-afce-5ed150da8404' | System | 28 Apr 2021 23:04:11 |
| User entered 'No (N)'  | System | 28 Apr 2021 23:04:11 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-04-28T10:45:39-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'aea02689-460d-420b-afce-5ed150da8404' | System | 28 Apr 2021 23:04:11 |
| User entered 'Yes (Y)'   | System | 28 Apr 2021 23:04:11 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-04-28T10:45:59-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'aea02689-460d-420b-afce-5ed150da8404' | System | 28 Apr 2021 23:04:11 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)'   | System | 28 Apr 2021 23:04:11 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Date and time of submission](#)

| Audit  | User   | Time (GMT)           |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-04-28T10:47:20-05:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: 'aea02689-460d-420b-afce-5ed150da8404' | System | 28 Apr 2021 23:04:11 |
| User entered '28 Apr 2021 10:47:20'  | System | 28 Apr 2021 23:04:11 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '24 Apr 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '28 Apr 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '01 May 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '05 May 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '08 May 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '12 May 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '15 May 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '19 May 2021 23:59' | System | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '22 May 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '26 May 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '29 May 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '02 Jun 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '05 Jun 2021 00:01' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '09 Jun 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '12 Jun 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '16 Jun 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '19 Jun 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '23 Jun 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '26 Jun 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '30 Jun 2021 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '03 Jul 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '07 Jul 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '10 Jul 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '14 Jul 2021 23:59' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '17 Jul 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '21 Jul 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '24 Jul 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '28 Jul 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '31 Jul 2021 00:01' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '04 Aug 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '07 Aug 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '11 Aug 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '14 Aug 2021 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '18 Aug 2021 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 19:19:23 |



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[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '21 Aug 2021 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '25 Aug 2021 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '28 Aug 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '01 Sep 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '04 Sep 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '08 Sep 2021 23:59' | System | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '11 Sep 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '15 Sep 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '18 Sep 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '22 Sep 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '25 Sep 2021 00:01' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '29 Sep 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '02 Oct 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '06 Oct 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '09 Oct 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '13 Oct 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '16 Oct 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '20 Oct 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '23 Oct 2021 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '27 Oct 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 19:19:23 |

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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 | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '30 Oct 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '03 Nov 2021 23:59' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '06 Nov 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '10 Nov 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '13 Nov 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '17 Nov 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '20 Nov 2021 00:01' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '24 Nov 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '27 Nov 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '01 Dec 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**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 | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '04 Dec 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '08 Dec 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '11 Dec 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '15 Dec 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '18 Dec 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '22 Dec 2021 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '25 Dec 2021 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '29 Dec 2021 23:59' | System | 19 Nov 2020 19:19:23 |



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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '01 Jan 2022 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '05 Jan 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '08 Jan 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '12 Jan 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '15 Jan 2022 00:01' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '19 Jan 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '22 Jan 2022 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '26 Jan 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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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 | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '29 Jan 2022 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '02 Feb 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '05 Feb 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '09 Feb 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '12 Feb 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '16 Feb 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '19 Feb 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '23 Feb 2022 23:59' | System | 19 Nov 2020 19:19:23 |



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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '26 Feb 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '02 Mar 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '05 Mar 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '09 Mar 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '12 Mar 2022 00:01' | System | 19 Nov 2020 19:19:23 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '16 Mar 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '19 Mar 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '23 Mar 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '26 Mar 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '30 Mar 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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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 | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 19:19:23 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '02 Apr 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '06 Apr 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '09 Apr 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '13 Apr 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '16 Apr 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '20 Apr 2022 23:59' | System | 19 Nov 2020 19:19:23 |



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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '23 Apr 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '27 Apr 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '30 Apr 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '04 May 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Form: Safety Follow Up Diary**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '07 May 2022 00:01' | System | 19 Nov 2020 19:19:23 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '11 May 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '14 May 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '18 May 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '21 May 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '25 May 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 19:19:23 |



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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '28 May 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '01 Jun 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 19:19:23 |

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[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '04 Jun 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '08 Jun 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '11 Jun 2022 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '15 Jun 2022 23:59' | System | 19 Nov 2020 19:19:23 |



**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '18 Jun 2022 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '22 Jun 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '25 Jun 2022 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '29 Jun 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '02 Jul 2022 00:01' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '06 Jul 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '09 Jul 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '13 Jul 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '16 Jul 2022 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '20 Jul 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '23 Jul 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '27 Jul 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '30 Jul 2022 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '03 Aug 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 19:19:23 |

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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 | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '06 Aug 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '10 Aug 2022 23:59' | System | 19 Nov 2020 19:19:23 |



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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '13 Aug 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '17 Aug 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '20 Aug 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '24 Aug 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '27 Aug 2022 00:01' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '31 Aug 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '03 Sep 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '07 Sep 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '10 Sep 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '14 Sep 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 19:19:23 |



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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '17 Sep 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '21 Sep 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '24 Sep 2022 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '28 Sep 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '01 Oct 2022 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '05 Oct 2022 23:59' | System | 19 Nov 2020 19:19:23 |



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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 09 Jun 2021 15:10:08**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '08 Oct 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '12 Oct 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 19:19:23 |

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '15 Oct 2022 00:01' | System | 19 Nov 2020 19:19:23 |

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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '19 Oct 2022 23:59' | System | 19 Nov 2020 19:19:23 |

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**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 19:19:23 |

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[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '22 Oct 2022 00:01' | System | 19 Nov 2020 19:19:23 |



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**Folder: New Safety Follow Up Diary (1)**

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| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '26 Oct 2022 23:59' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

**TIMEPOINT**

| Audit                                     | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.     | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Open Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '29 Oct 2022 00:01' | System | 19 Nov 2020 19:19:23 |

**US3092245**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:10:08**

[Patient Cloud Close Date & Time](#)

| Audit   | User   | Time (GMT)           |
|---|--------|----------------------|
| Amendment Manager: Data entry locked.               | System | 19 Nov 2020 19:19:23 |
| Amendment Manager: User entered '02 Nov 2022 23:59' | System | 19 Nov 2020 19:19:23 |

US3092245

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:10:08**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-02-27T11:17:10-06:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '761e6d4b-d7ad-4d97-ae0b-6198f919349d' User entered 'No (N)' | System           | 27 Feb 2021 17:18:52 |
|  | System           | 27 Feb 2021 17:18:52 |

**US3092245**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Date & Time of Submission](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 25 Apr 2021 23:49:46 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a4f05205e0ef3285)', Time: '2021-02-27T11:17:28-06:00', User OID: 'PatientReportedOutcome (US3092245)', ODM File OID: '761e6d4b-d7ad-4d97-ae0b-6198f919349d' User entered '27 Feb 2021 11:17:28' | System           | 27 Feb 2021 17:18:52 |
|  | System           | 27 Feb 2021 17:18:52 |

**US3092245**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:31:54 |

**US3092245**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 03 Apr 2021 23:19:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '24 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:31:54 |



**US3092245**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 03 Apr 2021 23:19:38 |
| User signature succeeded.                  | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:31:54 |

**US3092245**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:31:54 |

**US3092245**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 03 Apr 2021 23:19:38 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:31:59 |

**US3092245**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 23:19:38 |
| User entered 'I'  | System           | 24 Nov 2020 21:31:59 |

**US3092245**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 22:54:09 |

**US3092245**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '29 Dec 2020' | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 22:54:09 |

**US3092245**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded.                  | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 22:54:09 |

**US3092245**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 18 Jan 2021 22:54:09 |



**US3092245**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 22 Jan 2021 17:18:04 |

**US3092245**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 18:18:36 |
| User entered 'I'  | System           | 22 Jan 2021 17:18:04 |

**US3092245**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:16:01 |

**US3092245**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '27 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:16:01 |

**US3092245**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded.                  | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:16:01 |

**US3092245**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:16:01 |

**US3092245**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:16:07 |

**US3092245**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 18:18:36 |
| User entered 'I'  | System           | 27 Jan 2021 20:16:07 |



**US3092245**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 07 Mar 2021 18:32:02 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 16:35:23 |

**US3092245**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 07 Mar 2021 18:32:02 |
| User entered '23 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 16:35:23 |

**US3092245**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded.                  | Valentine Ebuh (b) (4)      | 07 Mar 2021 18:32:02 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 16:35:23 |

**US3092245**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 07 Mar 2021 18:32:02 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 16:35:23 |

**US3092245**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 14 Apr 2021 18:18:36 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 07 Mar 2021 18:32:02 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 26 Feb 2021 16:36:27 |

**US3092245**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 14 Apr 2021 18:18:36 |
| User entered 'I'  | System           | 26 Feb 2021 16:36:27 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:28:33 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '07 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:28:33 |



**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:28:33 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Folder OID](#)

| Audit                 | User   | Time (GMT)           |
|-----------------------|--------|----------------------|
| User entered 'VISIT4' | System | 08 Apr 2021 15:28:33 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:00 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '07 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:00 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '10:55'      | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:00 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Apr 2021 10:55' | System | 08 Apr 2021 15:29:00 |

US3092245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

Temperature (xxx.x)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '98.7' F     | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:00 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:00 |



**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:00 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '92'         | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:00 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 08 Apr 2021 15:29:00 |

US3092245

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '18'         | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:00 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 08 Apr 2021 15:29:00 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '132'        | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:00 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 08 Apr 2021 15:29:00 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '76'         | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:00 |



**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 08 Apr 2021 15:29:00 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:10:08**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:17 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:10:08**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '07 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:17 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:33 |

US3092245

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:08

Collection date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '07 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:33 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

**Collection time (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '11:39'      | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:33 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Apr 2021 11:39' | System | 08 Apr 2021 15:29:33 |

**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:29:40 |



**US3092245**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Apr 2021 15:29:40 |

**US3092245**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Was Contact Attempted?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Apr 2021 15:42:47 |
|                        |                  |                      |

**US3092245**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '27 Apr 2021' | (b) (4), (b) (6) | 30 Apr 2021 15:42:47 |
|                            |                  |                      |

**US3092245**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Please select one status for the follow-up contact](#)

| Audit                                      | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Contact Made (CONTACT MADE)' | (b) (4), (b) (6) | 30 Apr 2021 15:42:47 |

**US3092245**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Apr 2021 15:42:47 |

**US3092245**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Is the participant continuing to the next visit?](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'Yes (Y)' | (b) (4), (b) (6) | 30 Apr 2021 15:42:55 |
|                        |                  |                      |

**US3092245**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 30 Apr 2021 15:42:55 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Was this visit performed?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 09 Feb 2021 23:17:28 |



US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:08

[Visit date \(dd MMM yyyy\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '9 Feb 2021' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:17:28 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:10:08

[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 18:39:22 |
| User signature succeeded.      | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Clinic (Clinic)' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:17:28 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Folder OID](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'UNBLND_DECIDE' | System           | 09 Feb 2021 23:17:28 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:08

Date of updated informed consent (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '9 Feb 2021' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:00 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:10:08**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit                                      | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)       | 28 Apr 2021 18:39:22 |
| User signature succeeded.                  | Valentine Ebuh (b) (4) | 23 Mar 2021 22:52:09 |
| User entered '0' WR# 5295537               | (b) (4)                | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System                 | 06 Mar 2021 07:10:10 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:10:08**

[Was the participant unblinded?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:00 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:10:08**

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 28 Apr 2021 18:39:22 |
| User signature succeeded.   | Valentine Ebuh (b) (4) | 23 Mar 2021 22:52:09 |
| User entered 'AMENDMENT 6 OR LATER<br>(AMENDMENT 6 OR LATER)' WR# 5295537 | (b) (4)                | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint.                                | System                 | 06 Mar 2021 07:10:10 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:08

Date of unblinding (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '9 Feb 2021' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:00 |



US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:08

[Participant randomization assignment](#)

| Audit                            | User                     | Time (GMT)           |
|----------------------------------|--------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded.        | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Placebo (Placebo)' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:00 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:10:08**

[Actual Dose 1](#)

| Audit                            | User                     | Time (GMT)           |
|----------------------------------|--------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded.        | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Placebo (Placebo)' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:00 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:10:08**

[Actual Dose 2](#)

| Audit                            | User                     | Time (GMT)           |
|----------------------------------|--------------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded.        | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Placebo (Placebo)' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:00 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:10:08

[Will participant receive mRNA-1273?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:00 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:10:08**

[Placebo Only Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '1'  | System           | 09 Feb 2021 23:18:00 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing with mRNA-1273](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'I'  | System           | 09 Feb 2021 23:18:00 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:08

Height

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '152.4' cm   | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:08

Weight

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '383.6' lb   | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |



**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:10:08**

**BMI (xxx.x)**

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '75.07338'   | System           | 09 Feb 2021 23:21:44 |
| DataPoint set to visible. | System           | 09 Feb 2021 23:18:00 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:08

Height

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '152.4' cm   | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:08

Weight

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '383.6' lb   | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:10:08**

**BMI (xxx.x)**

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '75.07338'   | System           | 09 Feb 2021 23:21:44 |
| DataPoint set to visible. | System           | 09 Feb 2021 23:18:00 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Timepoint](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |
|  | (b) (4)                  |                      |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Were vital signs assessed?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '9 Feb 2021' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Time of assessment \(00:00-23:59\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '14:17'      | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |



**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '9 Feb 2021 14:17' | System           | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Temperature (xxx.x)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '97.2' F     | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Route of measurement](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Oral (Oral)' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[If Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse \(xxx\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '84'         | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'bpm' | System           | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '15'         | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'breaths/min' | System           | 09 Feb 2021 23:21:44 |



US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Systolic Blood Pressure (xxx)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '150'        | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'mmHg' | System           | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Diastolic Blood Pressure (xxx)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '90'         | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'mmHg' | System           | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:08

Height

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered '152.4' cm   | (b) (4)<br>Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:10:08

Weight

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '383.6' lb   | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 15:10:08**

**BMI (xxx.x)**

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '75.07338'   | System           | 09 Feb 2021 23:21:44 |
| DataPoint set to visible. | System           | 09 Feb 2021 23:18:00 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Timepoint](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6)                    | 28 Apr 2021 18:39:22 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Marissa Cervenka (b) (4)<br>(b) (4) | 09 Feb 2021 23:21:44 |



US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Were vital signs assessed?](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Date of assessment (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '9 Feb 2021' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

**Time of assessment (00:00-23:59)**

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered '15:38'      | (b) (4)<br>Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Vital Signs Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '9 Feb 2021 15:38' | System           | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Temperature (xxx.x)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '97.4' F     | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Route of measurement](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Oral (Oral)' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[If Other, specify](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse \(xxx\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '89'         | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |



**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'bpm' | System           | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '16'         | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'breaths/min' | System           | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Systolic Blood Pressure (xxx)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '154'        | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'mmHg' | System           | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Diastolic Blood Pressure (xxx)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '94'         | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:44 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'mmHg' | System           | 09 Feb 2021 23:21:44 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:08

[Was the physical examination performed?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:52 |



US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:10:08

Date of examination (dd MMM yyyy)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '9 Feb 2021' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:21:52 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[Was study treatment given?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 09 Feb 2021 23:22:21 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[If No, reason not given](#)

| Audit                     | User                                | Time (GMT)           |
|---------------------------|-------------------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)                    | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>Marissa Cervenka (b) (4) | 09 Feb 2021 23:22:21 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

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 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered empty.       | Marissa Cervenka (b) (4) | 09 Feb 2021 23:22:21 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[What was the study treatment? \(Unblinded\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'mRNA-1273'  | System           | 09 Feb 2021 23:22:21 |
| DataPoint set to visible. | System           | 09 Feb 2021 23:18:00 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

What was the treatment date? (dd MMM yyyy)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '9 Feb 2021' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:22:21 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '14:57'      | Marissa Cervenka (b) (4) | 09 Feb 2021 23:22:21 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[Treatment Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '9 Feb 2021 14:57' | System           | 09 Feb 2021 23:22:21 |



US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

[Which arm was used to give treatment?](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded.          | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Left Arm (LEFT ARM)' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:22:21 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'ONCE' | System           | 09 Feb 2021 23:22:21 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

What was the route of administration for the study treatment?

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'INTRAMUSCULAR' | System           | 09 Feb 2021 23:22:21 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:10:08

[Was the sample collected?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:26 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

**Collection date** (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '9 Feb 2021' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:26 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '14:54'      | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:26 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

[Collection date and time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '9 Feb 2021 14:54' | System           | 09 Feb 2021 23:18:26 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:10:08**

[Was the sample collected?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:42 |



**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:10:08**

[Collection date \(dd MMM yyyy\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '9 Feb 2021' | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:42 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:10:08**

**Collection time (00:00 - 23:59)**

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered '14:52'      | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:42 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:10:08**

[Collection Date and Time \(derived\)](#)

| Audit                           | User             | Time (GMT)           |
|---------------------------------|------------------|----------------------|
| Data hard locked.               | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '9 Feb 2021 14:52' | System           | 09 Feb 2021 23:18:42 |

US3092245

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:10:08

[Is the participant continuing to the next visit?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 09 Feb 2021 23:18:47 |

**US3092245**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '1'  | System           | 09 Feb 2021 23:18:47 |

**US3092245**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 16 Feb 2021 23:07:27 |

**US3092245**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '16 Feb 2021' | (b) (4)<br>(b) (4), (b) (6) | 16 Feb 2021 23:07:27 |

**US3092245**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded.                  | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 16 Feb 2021 23:07:27 |



**US3092245**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 16 Feb 2021 23:07:27 |

**US3092245**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 16 Feb 2021 23:09:07 |

**US3092245**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'I'  | System           | 16 Feb 2021 23:09:07 |

**US3092245**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[OLD29 Placebo Flag](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '1'          | System           | 16 Feb 2021 23:09:07 |
| DataPoint set to visible. | System           | 16 Feb 2021 23:09:07 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:43:57 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '09 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:43:57 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[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 18:39:22 |
| User signature succeeded.      | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:43:57 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Folder OID](#)

| Audit                | User             | Time (GMT)           |
|----------------------|------------------|----------------------|
| Data hard locked.    | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'OLD29' | System           | 12 Mar 2021 00:43:57 |



**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User accepted default value 'Pre-Dose (PREDOSE)' |                  | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '09 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '14:46'      | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '09 Mar 2021 14:46' | System           | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '97.3' F     | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |



**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '72'         | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'bpm' | System           | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '15'         | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'breaths/min' | System           | 12 Mar 2021 00:45:16 |

US3092245

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:10:08

Systolic Blood Pressure (xxx)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '129'        | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'mmHg' | System           | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '71'         | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'mmHg' | System           | 12 Mar 2021 00:45:16 |



**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Timepoint](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| Data hard locked.                                  | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User accepted default value 'Post-Dose (POSTDOSE)' |                  | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

US3092245

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

Date of assessment (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '09 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '15:26'      | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '09 Mar 2021 15:26' | System           | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Temperature \(xxx.x\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '97.8' F     | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |



**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '74'         | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse units](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'bpm' | System           | 12 Mar 2021 00:45:16 |

US3092245

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:10:08

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '18'         | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Respiratory Rate units](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'breaths/min' | System           | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '134'        | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Systolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'mmHg' | System           | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '69'         | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:16 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Diastolic Blood Pressure units](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'mmHg' | System           | 12 Mar 2021 00:45:16 |



**US3092245**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:10:08**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:26 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:10:08**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '09 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:26 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[Was study treatment given?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:45 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[If No, reason not given](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:45 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

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 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:45 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[What was the study treatment? \(Unblinded\)](#)

| Audit                     | User             | Time (GMT)           |
|---------------------------|------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'mRNA-1273'  | System           | 12 Mar 2021 00:45:45 |
| DataPoint set to visible. | System           | 16 Feb 2021 23:09:07 |

US3092245

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

What was the treatment date? (dd MMM yyyy)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '09 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:45 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[What was the treatment time? \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '14:56'      | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:45 |



**US3092245**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[Treatment Date and Time \(derived\)](#)

| Audit                            | User             | Time (GMT)           |
|----------------------------------|------------------|----------------------|
| Data hard locked.                | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered '09 Mar 2021 14:56' | System           | 12 Mar 2021 00:45:45 |

US3092245

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:10:08

Which arm was used to give treatment?

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded.          | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:45 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[What was the frequency of the study treatment dosing?](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'ONCE' | System           | 12 Mar 2021 00:45:45 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:10:08**

[What was the route of administration for the study treatment?](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| Data hard locked.            | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'INTRAMUSCULAR' | System           | 12 Mar 2021 00:45:45 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:45:50 |

**US3092245**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'I'  | System           | 12 Mar 2021 00:45:50 |

**US3092245**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Was Contact Attempted?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 21:30:54 |

**US3092245**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '17 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 21:30:54 |



**US3092245**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Please select one status for the follow-up contact](#)

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded.                  | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 21:30:54 |

**US3092245**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:10:08**

[Comments](#)

*If Contact Not Made, please provide Comments*

| Audit                                      | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.                          | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded.                  | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered '1ST ATTEMPT MADE ON 03/16/21 | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 21:30:54 |
| 2ND ATTEMPT MADE ON 03/17/21'              |                             |                      |

**US3092245**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Is the participant continuing to the next visit?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 28 Apr 2021 18:39:22 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 17 Mar 2021 21:30:59 |

**US3092245**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:10:08**

[Continuing Flag](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 18:39:22 |
| User entered 'I'  | System           | 17 Mar 2021 21:30:59 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Was this visit performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:18:45 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Visit date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '07 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:18:45 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Was visit performed at the participant's home or at the clinic?](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Clinic (Clinic)' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:18:45 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:10:08**

[Folder OID](#)

| Audit                | User   | Time (GMT)           |
|----------------------|--------|----------------------|
| User entered 'OLD57' | System | 08 Apr 2021 15:18:45 |



**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Were vital signs assessed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

**Date of assessment** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '07 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

**Time of assessment (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '10:55'      | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Vital Signs Date and Time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Apr 2021 10:55' | System | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

**Temperature (xxx.x)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '98.7' F     | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Route of measurement](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Oral (Oral)' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[If Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '92'         | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:24:54 |



**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Pulse units](#)

| Audit              | User   | Time (GMT)           |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Respiratory Rate \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '18'         | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Respiratory Rate units](#)

| Audit                      | User   | Time (GMT)           |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Systolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '132'        | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Systolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Diastolic Blood Pressure \(xxx\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '76'         | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:10:08**

[Diastolic Blood Pressure units](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 08 Apr 2021 15:24:54 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:10:08**

[Was the physical examination performed?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:25:05 |



**US3092245**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:10:08**

**Date of examination (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '07 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:25:05 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

[Was the sample collected?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:25:41 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

**Collection date** (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '07 Apr 2021' | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:25:41 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

[Collection time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '11:39'      | (b) (4)<br>(b) (4), (b) (6) | 08 Apr 2021 15:25:41 |

**US3092245**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:10:08**

[Collection date and time \(derived\)](#)

| Audit                            | User   | Time (GMT)           |
|----------------------------------|--------|----------------------|
| User entered '07 Apr 2021 11:39' | System | 08 Apr 2021 15:25:41 |

US3092245

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:10:08

[Did the participant experience any adverse events?](#)

| Audit   | User                              | Time (GMT)                                   |
|---|-----------------------------------|--|
| Data hard locked.   | (b) (4), (b) (6)                  | 03 May 2021 07:31:32                         |
| User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 131, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Per Safety Follow-up Diary Day 131, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'AES HAVE BEEN ENTERED IN EDC.' (Site from DM). | Vicki Martinez (b) (4)<br>(b) (4) | 15 Apr 2021 14:50:30<br>10 Apr 2021 20:56:48 |
| User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 131, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).   | (b) (4), (b) (6)                  | 02 Apr 2021 11:43:21                         |
| User signature succeeded.   | Valentine Ebuh (b) (4)<br>(b) (4) | 23 Feb 2021 03:47:23                         |
| User entered 'Yes (Y)'  | (b) (4), (b) (6)                  | 24 Nov 2020 21:41:23                         |

US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

[AEID](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.                              | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| Reviewed for Safety.                                   | (b) (4)<br>(b) (4), (b) (6) | 05 Apr 2021 12:23:27 |
| Un-reviewed for Safety.                                |                             | 01 Apr 2021 14:24:30 |
| DataPoint Un-verified.                                 |                             | 01 Apr 2021 14:24:30 |
| Signature has been broken.                             |                             | 01 Apr 2021 14:24:30 |
| User entered empty; reason for change Data Entry Error |                             | 01 Apr 2021 14:24:30 |
| Reviewed for Safety.                                   |                             | 12 Mar 2021 16:57:55 |
| DataPoint Verified.                                    |                             | 04 Mar 2021 22:12:28 |
| User signature succeeded.                              | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered   | (b) (4)                     | 25 Nov 2020 16:03:25 |
| 'USA-US086-2020-mRNA-1273-P301000007'                  | System                      | 25 Nov 2020 16:03:25 |
| User entered 'New'                                     | (b) (4), (b) (6)            | 25 Nov 2020 16:03:25 |

US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

[Adverse event](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                  | 20 Apr 2021 20:20:23 |
| User signature succeeded.   | Valentine Ebuh (b) (4)            | 14 Apr 2021 01:03:51 |
| User closed query 'PV Query: please confirm if the non-serious event of motor vehicle accident should be merged and subsumed under the serious event of chest pain traumatic. If so, please merge both the events as one event: 'chest pain due to motor vehicle accident' they have the same onset date and end date. Please update the EDC accordingly.' (Site from Safety).  | (b) (4)<br>(b) (4), (b) (6)       | 12 Apr 2021 10:09:14 |
| User closed query 'PV Query Urgent: Please update the event term to final diagnosis (AE line #8 - Chest Pain Traumatic). Please update all information to correspond with this update and delete AE line #8. ' (Site from Safety).  | (b) (4), (b) (6)                  | 12 Apr 2021 10:08:39 |
| Query 'PV Query: please confirm if the non-serious event of motor vehicle accident should be merged and subsumed under the serious event of chest pain traumatic. If so, please merge both the events as one event: 'chest pain due to motor vehicle accident' they have the same onset date and end date. Please update the EDC accordingly.' answered with 'CHEST PAIN TRAUMATIC DUE TO MOTOR VEHICLE ACCIDENT HAS A SEPERATE END DATE. ORIGINAL DATA IS CORRECT' (Site from Safety). | Vicki Martinez (b) (4)<br>(b) (4) | 10 Apr 2021 20:58:51 |
| Query 'PV Query Urgent: Please update the event term to final diagnosis (AE line #8 - Chest Pain Traumatic). Please update all information to correspond with this update and delete AE line #8. ' answered with 'ORIGINAL DATA IS CORRECT' (Site from Safety).   | Vicki Martinez (b) (4)<br>(b) (4) | 10 Apr 2021 20:58:06 |
| User opened query 'PV Query: please confirm if the non-serious event of motor vehicle accident should be merged and subsumed under the serious event of chest pain traumatic. If so, please merge both the events as one event: 'chest pain due to motor vehicle accident' they have the same onset date and end date. Please update the EDC accordingly.' (Site from Safety).  | (b) (4), (b) (6)                  | 05 Apr 2021 21:16:38 |



US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

[Adverse event](#)

| Audit  | User                  | Time (GMT)           |
|--|-----------------------|----------------------|
| User opened query 'PV Query Urgent: Please update the event term to final diagnosis (AE line #8 - Chest Pain Traumatic). Please update all information to correspond with this update and delete AE line #8. ' (Site from Safety).   | (b) (4), (b) (6)      | 02 Apr 2021 18:52:21 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\23.0.  | Coder Import (b) (4)  | 31 Mar 2021 22:53:06 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)  | 31 Mar 2021 22:53:06 |
| Data point term sent to Coder  | System                | 31 Mar 2021 22:52:34 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\23.0.  | Coder Import (b) (4)  | 31 Mar 2021 22:52:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.  | Coder Import (b) (4)  | 31 Mar 2021 22:52:17 |
| Query 'Per CDM Coding: for AE term CHEST PAIN DUE TO MOTOR VEHICLE ACCIDENT, Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of MOTOR VEHICLE ACCIDENT and one of CHEST PAIN traumatic etc.' canceled (Site from System).    | Coder Import (b) (4)  | 31 Mar 2021 22:52:08 |
| Data point term sent to Coder  | System                | 31 Mar 2021 22:51:33 |
| Signature has been broken.   | (b) (4), (b) (6)      | 31 Mar 2021 22:51:12 |
| User entered 'MOTOR VEHICLE ACCIDENT' reason for change: Data Entry Error  | (b) (4), (b) (6)      | 31 Mar 2021 22:51:12 |
| User opened query 'Per CDM Coding: for AE term CHEST PAIN DUE TO MOTOR VEHICLE ACCIDENT, Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of MOTOR VEHICLE ACCIDENT and one of CHEST PAIN traumatic etc.' (Site from System). | Coder Import (b) (4)  | 29 Mar 2021 06:46:59 |
| User signature succeeded.  | Valentine Ebu (b) (4) | 28 Mar 2021 01:06:13 |
| Data point term sent to Coder  | System                | 26 Mar 2021 22:21:56 |

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

[Adverse event](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Un-verified.   | Marissa Cervenka (b) (4) | 26 Mar 2021 22:21:21 |
| Coding entries removed.  | Marissa Cervenka (b) (4) | 26 Mar 2021 22:21:21 |
| Signature has been broken.   | Marissa Cervenka (b) (4) | 26 Mar 2021 22:21:21 |
| User entered 'CHEST PAIN DUE TO MOTOR VEHICLE ACCIDENT' reason for change: Data Entry Error  | Marissa Cervenka (b) (4) | 26 Mar 2021 22:21:21 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 04 Mar 2021 22:12:28 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\\23.0. | Coder Import (b) (4)     | 24 Nov 2020 21:54:40 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.   | Coder Import (b) (4)     | 24 Nov 2020 21:54:40 |
| Data point term sent to Coder  | System                   | 24 Nov 2020 21:52:58 |
| User entered 'MOTOR VEHICLE ACCIDENT'  | (b) (4), (b) (6)         | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this a medically-attended AE?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '21 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 24 Nov 2020 21:52:21 |



**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)         | 04 Mar 2021 22:12:28 |
| User signature succeeded.   | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | (b) (4)                  | 18 Dec 2020 23:02:43 |
| User entered 'No (N)' reason for change: Data Entry Error   | System                   | 18 Dec 2020 23:02:43 |
| User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | destiny robinson (b) (4) | 18 Dec 2020 23:02:28 |
| User entered 'Yes (Y)'  | (b) (4)                  | 18 Dec 2020 23:02:28 |
|   | (b) (4), (b) (6)         | 24 Nov 2020 21:52:21 |

US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

If not Ongoing, end date (dd MMM yyyy)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| Signature has been broken.   | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 22:51:12 |
| User entered '21 Nov 2020' reason for change: Data Entry Error   |                             | 31 Mar 2021 22:51:12 |
| User closed query 'Per DM CLR: Please review the dates of this AE as an event of a Motor Vehicle Accident is not expected to have a duration of more than a single date. Please review and update the dates as appropriate. Otherwise, clarify.' (Site from DM).                 |                             | 31 Mar 2021 01:20:13 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered '25 Nov 2020' reason for change: Data Entry Error   | (b) (4)                     |                      |
| Query 'Per DM CLR: Please review the dates of this AE as an event of a Motor Vehicle Accident is not expected to have a duration of more than a single date. Please review and update the dates as appropriate. Otherwise, clarify.' answered with '21 NOV 2020' (Site from DM). | Marissa Cervenka (b) (4)    | 26 Mar 2021 22:21:21 |
| DataPoint Un-verified.   | (b) (4)                     |                      |
| Signature has been broken.   | Valentine Ebuh (b) (4)      | 26 Mar 2021 19:11:47 |
| User entered '21 Nov 2020' reason for change: Data Entry Error   | (b) (4)                     |                      |
| User opened query 'Per DM CLR: Please review the dates of this AE as an event of a Motor Vehicle Accident is not expected to have a duration of more than a single date. Please review and update the dates as appropriate. Otherwise, clarify.' (Site from DM).                 | Valentine Ebuh (b) (4)      | 26 Mar 2021 18:46:19 |
| DataPoint Verified.  | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).   | (b) (4)<br>System           | 18 Dec 2020 23:02:28 |

US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

If not Ongoing, end date (dd MMM yyyy)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). | System                   | 18 Dec 2020 23:02:28 |
| User entered '25 Nov 2020' reason for change: Data Entry Error   | destiny robinson (b) (4) | 18 Dec 2020 23:02:28 |
| User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).             | (b) (4)                  | 18 Dec 2020 23:02:01 |
| User entered empty.  | (b) (4), (b) (6)         | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[End time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[AE End Date and Time \(derived\)](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| Query 'PV Query: Please provide the event stop date, when available.' canceled (Site from Safety).    | (b) (4), (b) (6) | 21 Dec 2020 16:22:46 |
| User opened query 'PV Query: Please provide the event stop date, when available.' (Site from Safety). |                  | 04 Dec 2020 19:59:01 |
| User entered empty.   | System           | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Severity](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.                                | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded.                          | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

[Is the adverse event serious?](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                  | 20 Apr 2021 20:20:23 |
| User signature succeeded.   | Valentine Ebuh (b) (4)            | 14 Apr 2021 01:03:51 |
| User closed query 'PV Urgent Query: Please update the event term to final diagnosis (AE line #8 - CHEST PAIN TRAUMATIC). Please update all information to correspond with this update and delete AE line #8.' (Site from Safety).                             | (b) (4)<br>(b) (4), (b) (6)       | 05 Apr 2021 12:22:16 |
| Query 'PV Urgent Query: Please update the event term to final diagnosis (AE line #8 - CHEST PAIN TRAUMATIC). Please update all information to correspond with this update and delete AE line #8.' answered with 'pending medical records' (Site from Safety). | Vicki Martinez (b) (4)<br>(b) (4) | 02 Apr 2021 18:20:12 |
| User opened query 'PV Urgent Query: Please update the event term to final diagnosis (AE line #8 - CHEST PAIN TRAUMATIC). Please update all information to correspond with this update and delete AE line #8.' (Site from Safety).                             | (b) (4), (b) (6)                  | 02 Apr 2021 17:43:05 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).  | System                            | 31 Mar 2021 22:54:27 |
| DataPoint Un-verified.  | (b) (4), (b) (6)                  | 31 Mar 2021 22:54:27 |
| Signature has been broken.  |                                   | 31 Mar 2021 22:54:27 |
| User entered 'No (N)' reason for change: Data Entry Error   |                                   | 31 Mar 2021 22:54:27 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).  | System                            | 31 Mar 2021 22:51:12 |
| DataPoint Verified.   | (b) (4), (b) (6)                  | 04 Mar 2021 22:12:28 |
| User signature succeeded.   | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'  | (b) (4)<br>(b) (4), (b) (6)       | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |



**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

Requires inpatient or prolongation of existing Hospitalization

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.   | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| DataPoint Un-verified.  | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 22:51:12 |
| Signature has been broken.  |                             | 31 Mar 2021 22:51:12 |
| User entered '0' reason for change: Data Entry Error  |                             | 31 Mar 2021 22:51:12 |
| User closed query 'Per CDM: Please note that when Requires inpatient or prolongation of existing Hospitalization is checked, the Admitted to ICU field below needs to be completed with Yes or No and not left empty. Review and update accordingly. ' (Site from DM).          |                             | 31 Mar 2021 01:20:36 |
| Query 'Per CDM: Please note that when Requires inpatient or prolongation of existing Hospitalization is checked, the Admitted to ICU field below needs to be completed with Yes or No and not left empty. Review and update accordingly. ' answered with 'DONE' (Site from DM). | Marissa Cervenka (b) (4)    | 26 Mar 2021 22:21:31 |
| User opened query 'Per CDM: Please note that when Requires inpatient or prolongation of existing Hospitalization is checked, the Admitted to ICU field below needs to be completed with Yes or No and not left empty. Review and update accordingly. ' (Site from DM).          | (b) (4), (b) (6)            | 22 Mar 2021 14:01:07 |
| DataPoint Verified.   | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded.   | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| 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)<br>(b) (4), (b) (6) | 21 Dec 2020 09:36:55 |
| 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 'information has been entered' (Site from System).      | destiny robinson (b) (4)    | 18 Dec 2020 23:01:28 |

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EAB) (1725)

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US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| 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           | 18 Dec 2020 23:01:06 |
| 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) | 25 Nov 2020 19:19:13 |
| 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 'NO DISCHARGE DATE AS OF YET, PER SUBJECT STILL HOSPITALIZED.' (Site from System). | (b) (4), (b) (6) | 24 Nov 2020 22:06:13 |
| 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           | 24 Nov 2020 21:52:21 |
| User entered 'I'   | (b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

Hospital Admission Date (dd MMM yyyy)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.                              | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| DataPoint Un-verified.                                 | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 22:51:12 |
| Signature has been broken.                             |                             | 31 Mar 2021 22:51:12 |
| User entered empty; reason for change Data Entry Error |                             | 31 Mar 2021 22:51:12 |
| DataPoint Verified.                                    |                             | 04 Mar 2021 22:12:28 |
| User signature succeeded.                              | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '21 Nov 2020'                             | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

Hospital Discharge Date (dd MMM yyyy)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                    | 20 Apr 2021 20:20:23 |
| User signature succeeded.  | Valentine Ebuh (b) (4)              | 14 Apr 2021 01:03:51 |
| DataPoint Un-verified.   | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 22:51:12 |
| Signature has been broken.   |                                     | 31 Mar 2021 22:51:12 |
| User entered empty; reason for change Data Entry Error   |                                     | 31 Mar 2021 22:51:12 |
| DataPoint Verified.  |                                     | 04 Mar 2021 22:12:28 |
| User signature succeeded.  | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).                                   | (b) (4)<br>(b) (4), (b) (6)         | 21 Dec 2020 16:22:51 |
| Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'information has been entered ' (Site from Safety). | destiny robinson (b) (4)<br>(b) (4) | 18 Dec 2020 23:01:36 |
| User entered '25 Nov 2020' reason for change: Data Entry Error   | destiny robinson (b) (4)<br>(b) (4) | 18 Dec 2020 23:01:06 |
| User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).                                   | (b) (4), (b) (6)                    | 04 Dec 2020 19:57:32 |
| User entered empty.  | (b) (4), (b) (6)                    | 24 Nov 2020 21:52:21 |

US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

[Admitted to ICU?](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)                    | 20 Apr 2021 20:20:23 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)              | 14 Apr 2021 01:03:51 |
| Signature has been broken.                                | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 22:51:12 |
| User entered empty; reason for change Data Entry Error    |                                     | 31 Mar 2021 22:51:12 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)              | 28 Mar 2021 01:06:13 |
| DataPoint Un-verified.                                    | (b) (4)<br>Marissa Cervenka (b) (4) | 26 Mar 2021 22:21:21 |
| Signature has been broken.                                | (b) (4)<br>Marissa Cervenka (b) (4) | 26 Mar 2021 22:21:21 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)<br>Marissa Cervenka (b) (4) | 26 Mar 2021 22:21:21 |
| DataPoint Verified.                                       | (b) (4), (b) (6)                    | 04 Mar 2021 22:12:28 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered empty.                                       | (b) (4)<br>(b) (4), (b) (6)         | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |



**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Relationship to investigational product](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded.                | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Relationship to Study Procedure](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded.                | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Action taken with investigational product](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded.                      | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

None

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| Signature has been broken.   | (b) (4)<br>(b) (4), (b) (6) | 22 Apr 2021 15:01:23 |
| DataPoint Verified.  |                             | 20 Apr 2021 20:20:23 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| Signature has been broken.   | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 22:51:12 |
| User entered '1' reason for change: Data Entry Error   |                             | 31 Mar 2021 22:51:12 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System). | (b) (4)                     | 12 Mar 2021 00:48:13 |
| DataPoint Un-verified.   | (b) (4), (b) (6)            | 12 Mar 2021 00:48:13 |
| Signature has been broken.   |                             | 12 Mar 2021 00:48:13 |
| User entered '0' reason for change: Data Entry Error   |                             | 12 Mar 2021 00:48:13 |
| User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).        | System                      | 12 Mar 2021 00:48:01 |
| DataPoint Verified.  | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '1'   | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

[Concomitant Medication](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.                                  | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.                            | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| Signature has been broken.                           | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 22:51:12 |
| User entered '0' reason for change: Data Entry Error |                             | 31 Mar 2021 22:51:12 |
| User signature succeeded.                            | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| DataPoint Un-verified.                               | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 00:48:01 |
| Signature has been broken.                           |                             | 12 Mar 2021 00:48:01 |
| User entered '1' reason for change: Data Entry Error |                             | 12 Mar 2021 00:48:01 |
| DataPoint Verified.                                  |                             | 04 Mar 2021 22:12:28 |
| User signature succeeded.                            | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '0'                                     | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Concomitant Procedure](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:12:28 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 24 Nov 2020 21:52:21 |



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

[Outcome](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System). | (b) (4)                  |                      |
| User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System). | System                   | 26 Mar 2021 22:26:24 |
| DataPoint Un-verified.   | Marissa Cervenka (b) (4) | 26 Mar 2021 22:21:21 |
| Signature has been broken.   | (b) (4)                  |                      |
|  | Marissa Cervenka (b) (4) | 26 Mar 2021 22:21:21 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error   | (b) (4)                  |                      |
| DataPoint Verified.  | (b) (4), (b) (6)         | 04 Mar 2021 22:12:28 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|  | (b) (4)                  |                      |
| User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System). | System                   | 18 Dec 2020 23:02:01 |
| User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error                     | destiny robinson (b) (4) | 18 Dec 2020 23:02:01 |
|  | (b) (4)                  |                      |
| User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System). | System                   | 18 Dec 2020 23:01:06 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'   | (b) (4), (b) (6)         | 24 Nov 2020 21:52:21 |
|  |                          |                      |

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| DataPoint Un-verified.   | (b) (4)                  |                      |
|  | Marissa Cervenka (b) (4) | 26 Mar 2021 22:26:24 |
| Signature has been broken.   | (b) (4)                  |                      |
|  | Marissa Cervenka (b) (4) | 26 Mar 2021 22:26:24 |
| User entered empty; reason for change Data Entry Error   | (b) (4)                  |                      |
|  | Marissa Cervenka (b) (4) | 26 Mar 2021 22:26:24 |
| DataPoint Verified.  | (b) (4), (b) (6)         | 04 Mar 2021 22:12:28 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|  | (b) (4)                  |                      |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).                                   | (b) (4), (b) (6)         | 21 Dec 2020 16:23:00 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'information has been entered ' (Site from Safety). | destiny robinson (b) (4) | 18 Dec 2020 23:01:47 |
|  | (b) (4)                  |                      |
| User entered 'subject is home and has home rehab therapy visits' reason for change: Data Entry Error   | destiny robinson (b) (4) | 18 Dec 2020 23:01:06 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).                                   | (b) (4)                  |                      |
|  | (b) (4), (b) (6)         | 04 Dec 2020 19:58:22 |
|  |                          |                      |
| User entered empty.  | (b) (4), (b) (6)         | 24 Nov 2020 21:52:21 |
|  |                          |                      |

US3092245

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:10:08

[Narrative](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                    | 20 Apr 2021 20:20:23 |
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 14 Apr 2021 01:03:51 |
| DataPoint Un-verified.  | (b) (4)<br>Vicki Martinez (b) (4)   | 10 Apr 2021 20:59:09 |
| Signature has been broken.  | (b) (4)<br>Vicki Martinez (b) (4)   | 10 Apr 2021 20:59:09 |
| User entered 'SUBJECT STATES SHE IS STILL ADMITTED IN THE HOSPITAL. SHE STATES THAT SHE HAS LEFT SHOULDER, LEFT NECK AND LEFT ANKLE PAIN. BUT NO FRACTURES FROM THE MOTOR VEHICLE ACCIDENT. SUBJECT STATES THAT SHE WILL BE GOING TO REHAB FACILITY AFTER DISCHARGE FROM HOSPITAL.' reason for change: New Information  | Vicki Martinez (b) (4)<br>(b) (4)   | 10 Apr 2021 20:59:09 |
| User closed query 'Per DM CLR: Narrative indicates that the subject HAS LEFT SHOULDER, LEFT NECK AND LEFT ANKLE PAIN. However, there are no corresponding AE record that match the information. Please review and update to record the corresponding AEs as appropriate. Otherwise, clarify.' (Site from DM).   | (b) (4), (b) (6)                    | 31 Mar 2021 01:24:34 |
| Query 'Per DM CLR: Narrative indicates that the subject HAS LEFT SHOULDER, LEFT NECK AND LEFT ANKLE PAIN. However, there are no corresponding AE record that match the information. Please review and update to record the corresponding AEs as appropriate. Otherwise, clarify.' answered with 'MEDICAL RECORDS WERE REVIEWED. PRIMARY REASON FOR HOSPITALIZATION HAS BEEN UPDATED. ADDITIONAL COMPLAINTS UPDATED IN SOURCE/ECRF.' (Site from DM). | Marissa Cervenka (b) (4)<br>(b) (4) | 26 Mar 2021 22:21:03 |
| User opened query 'Per DM CLR: Narrative indicates that the subject HAS LEFT SHOULDER, LEFT NECK AND LEFT ANKLE PAIN. However, there are no corresponding AE record that match the information. Please review and update to record the corresponding AEs as appropriate. Otherwise, clarify.' (Site from DM).   | (b) (4), (b) (6)                    | 20 Mar 2021 07:22:40 |

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Narrative](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)       | 04 Mar 2021 22:12:28 |
| User signature succeeded.   | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).   | (b) (4)<br>System      | 24 Nov 2020 22:10:32 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).   | System                 | 24 Nov 2020 22:10:32 |
| User entered 'Subject states she is still admitted in the hospital. She states that she has left shoulder, left neck and left ankle pain. But no fractures from the motor vehicle accident. Subject states that she will be going o rehab facility after discharge from hospital.' reason for change: New Information | (b) (4), (b) (6)       | 24 Nov 2020 22:10:32 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).   | System                 | 24 Nov 2020 21:52:21 |
| User entered empty.   | (b) (4), (b) (6)       | 24 Nov 2020 21:52:21 |

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 31 Mar 2021 22:54:27 |
| User entered '1' | System | 24 Nov 2020 21:52:21 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 24 Nov 2020 21:52:21 |

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 26 Mar 2021 22:21:21 |

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:10:08

[Adverse event](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 14 Apr 2021 01:03:51 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Post-traumatic pain, LLT: Post-traumatic pain - version MedDRA\23.0. | Coder Import (b) (4)     | 05 Apr 2021 16:05:06 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.   | Coder Import (b) (4)     | 05 Apr 2021 16:05:06 |
| Data point term sent to Coder  | System                   | 01 Apr 2021 17:07:30 |
| Signature has been broken.   | (b) (4), (b) (6)         | 01 Apr 2021 17:06:38 |
| User entered 'MULTIPLE TRAUMAS DUE TO MOTOR VEHICLE ACCIDENT (LEFT SHOULDER, LEFT NECK AND LEFT ANKLE PAIN)' reason for change: Data Entry Error   |                          | 01 Apr 2021 17:06:38 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| Data point term sent to Coder  | System                   | 26 Mar 2021 22:26:01 |
| User entered 'MULTIPLE TRAUMAS DUE TO MOTOR VEHICLE ACCIDENT. (LEFT SHOULDER, LEFT NECK AND LEFT ANKLE PAIN)'  | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |



**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Was this a medically-attended AE?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered '21 Nov 2020' | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered empty.       | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered empty.       | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[End time \(00:00-23:59\)](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered empty.       | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Severity](#)

| Audit                                      | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.                        | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded.                  | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Is the adverse event serious?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered '0'          | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered '0'          | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered '0'          | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

US3092245

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:10:08

Hospital Admission Date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered empty.       | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |



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Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:10:08

Hospital Discharge Date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered empty.       | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Admitted to ICU?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered empty.       | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

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Folder: Adverse Events

Form: Adverse Events (7)

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[Number of Days in ICU](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered empty.       | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered '0'          | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

US3092245

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:10:08

[Congenital anomaly or birth defect](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered '0'          | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Other medically important event](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered '0'          | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Relationship to investigational product](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded.                | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered 'Not Related (NOT RELATED)' | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Relationship to Study Procedure](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded.                | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered 'Not Related (NOT RELATED)' | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Action taken with investigational product](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded.                      | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[None](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered '0'          | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Concomitant Medication](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered 'I'          | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Concomitant Procedure](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered '0'          | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Outcome](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded.                                  | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered empty.       | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Narrative](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)         | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 28 Mar 2021 01:06:13 |
| User entered empty.       | Marissa Cervenka (b) (4) | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 26 Mar 2021 22:25:26 |



**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 26 Mar 2021 22:25:26 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[AEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.   | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| Reviewed for Safety.  | (b) (4)<br>(b) (4), (b) (6) | 12 Apr 2021 18:45:47 |
| User entered<br>'USA-US086-2020-mRNA-1273-P301000007'<br>reason for change: New Information |                             | 05 Apr 2021 15:47:43 |
| User entered<br>'USA-US086-2021-mRNA-1273-P301000014'                                       | System                      | 02 Apr 2021 19:03:59 |
| User entered 'New' reason for change: New<br>Information                                    | (b) (4), (b) (6)            | 02 Apr 2021 19:03:59 |
| User entered<br>'USA-US086-2020-mRNA-1273-P301000007'                                       |                             | 02 Apr 2021 12:55:42 |

US3092245

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:10:08

[Adverse event](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                  | 20 Apr 2021 20:20:23 |
| User signature succeeded.   | Valentine Ebuh (b) (4)            | 14 Apr 2021 01:03:51 |
| User closed query 'PV Query Urgent: Please delete this event as this is in correlation to AE#1. Please update AE line #1 and correspondingly delete after actioning. Thank you.' (Site from Safety).  | (b) (4)<br>(b) (4), (b) (6)       | 12 Apr 2021 18:45:24 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Post-traumatic pain, LLT: Post-traumatic pain - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4)   | 12 Apr 2021 13:58:00 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4)   | 12 Apr 2021 13:58:00 |
| Data point term sent to Coder   | System                            | 10 Apr 2021 20:54:08 |
| Query 'PV Query Urgent: Please delete this event as this is in correlation to AE#1. Please update AE line #1 and correspondingly delete after actioning. Thank you.' answered with 'CHEST PAIN TRAUMATIC DUE TO MOTOR VEHICLE ACCIDENT HAS A SEPERATE END DATE. CONFIRM DATA IS CORRECT.' (Site from Safety). | Vicki Martinez (b) (4)<br>(b) (4) | 10 Apr 2021 20:53:57 |
| User entered 'CHEST PAIN TRAUMATIC DUE TO MOTOR VEHICLE ACCIDENT' reason for change:  | Vicki Martinez (b) (4)<br>(b) (4) | 10 Apr 2021 20:53:53 |
| Data Entry Error  |                                   |                      |
| Data point term sent to Coder   | System                            | 10 Apr 2021 20:40:05 |
| Coding entries removed.   | Vicki Martinez (b) (4)<br>(b) (4) | 10 Apr 2021 20:40:02 |
| User entered 'CHEST PAIN TRAUMATIC DUE TO MOTOR VEHICLE ACCIDENT' reason for change: Data Entry Error   | Vicki Martinez (b) (4)<br>(b) (4) | 10 Apr 2021 20:40:02 |
| Comment added 'PI would like a call back regarding this Subject. He is available now- 6:00 PM CST. He can be reached at (b) (6) .   | Vicki Martinez (b) (4)<br>(b) (4) | 05 Apr 2021 18:28:15 |
| User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Post-traumatic pain, LLT: Post-traumatic pain - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4)   | 05 Apr 2021 16:03:31 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.  | Coder Import (b) (4)<br>(b) (4)   | 05 Apr 2021 16:03:31 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3092245

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:10:08

[Adverse event](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User opened query 'PV Query Urgent: Please delete this event as this is in correlation to AE#1. Please update AE line #1 and correspondingly delete after actioning. Thank you.' (Site from Safety). Data point term sent to Coder | (b) (4), (b) (6) | 02 Apr 2021 18:53:26 |
| User entered 'CHEST PAIN TRAUMATIC'  | System           | 01 Apr 2021 17:10:33 |
|  | (b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this a medically-attended AE?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this a Solicited Adverse Reaction?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '21 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |



**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Start time \(00:00-23:59\)](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[AE start date and time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '25 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

**End time (00:00-23:59)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[AE End Date and Time \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Severity](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.                                | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.                          | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

US3092245

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:10:08

[Is the adverse event serious?](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)       | 20 Apr 2021 20:20:23 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 14 Apr 2021 01:03:51 |
| User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | (b) (4)<br>System      | 01 Apr 2021 17:17:19 |
| User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System). | System                 | 01 Apr 2021 17:09:42 |
| User entered 'Yes (Y)'   | (b) (4), (b) (6)       | 01 Apr 2021 17:09:42 |



**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

US3092245

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:10:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)       | 20 Apr 2021 20:20:23 |
| User signature succeeded.   | Valentine Ebuh (b) (4) | 14 Apr 2021 01:03:51 |
| 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)                | 01 Apr 2021 17:25:10 |
| 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 by data change (Site from System). | System                 | 01 Apr 2021 17:25:10 |
| 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                 | 01 Apr 2021 17:17:19 |
| User entered '1' reason for change: Data Entry Error  | (b) (4), (b) (6)       | 01 Apr 2021 17:17:19 |
| User entered '0'  |                        | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

**Hospital Admission Date** (*dd MMM yyyy*)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.                                      | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '21 Nov 2020' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:17:19 |
| User entered empty.  |                             | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

**Hospital Discharge Date (dd MMM yyyy)**

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.                                      | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '25 Nov 2020' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:17:19 |
| User entered empty.  |                             | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Admitted to ICU?](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:25:10 |
| User entered empty.                                       |                             | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Number of Days in ICU](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |



**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Relationship to investigational product](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.                | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Relationship to Study Procedure](#)

| Audit                                    | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.                      | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.                | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Not Related (NOT RELATED)' | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Action taken with investigational product](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.                            | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.                      | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[None](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Concomitant Medication](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Concomitant Procedure](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Outcome](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| DataPoint Verified.                                    | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded.                              | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:20:23 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:10:08

[Narrative](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)                  | 20 Apr 2021 20:20:23 |
| User signature succeeded.   | Valentine Ebuh (b) (4)            | 14 Apr 2021 01:03:51 |
| 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)<br>(b) (4), (b) (6)       | 12 Apr 2021 18:45:31 |
| 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 'COVID-19 RAPID TEST COMPLETED ON 11/24/21. RESULTS WERE NEGATIVE.' (Site from Safety).  | Vicki Martinez (b) (4)<br>(b) (4) | 10 Apr 2021 20:56:11 |
| User entered 'SUBJECT STATES SHE WAS WAITING FOR HER HUSBAND TO PULL OUT THE CAR AND AS HE WAS BACKING OUT, HE DID NOT NOTICE HER AND WAS HIT WITH THE CAR. SHE REPORTS BEING HIT AND FALLING ON THE LEFT SIDE. AT THE ER, SHE STARTED HAVING SOME CHEST PAIN AND WAS ADMITTED WITH THE ABOVE DIAGNOSIS ON THE MEDICAL FLOOR. SHE WAS ADMITTED FOR PAIN MANAGEMENT, CHEST PAIN IMPROVED AND DETERMINED MUSCULOSKELETAL IN ETIOLOGY AND NON-CARDIAC. PHYSICAL THERAPY AND OCCUPATIONAL THERAPY.' reason for change: Data Entry Error | Vicki Martinez (b) (4)<br>(b) (4) | 10 Apr 2021 20:40:02 |
| 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 21:17:54 |
| User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).   | System                            | 01 Apr 2021 17:35:23 |
| Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).   | System                            | 01 Apr 2021 17:35:23 |

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3092245

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:10:08

[Narrative](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User entered 'SUBJECT STATES SHE WAS WAITING FOR HER HUSBAND TO PULL OUT THE CAR AND AS HE WAS BACKING OUT, HE DID NOT NOTICE HER AND WAS HIT WITH THE CAR. SHE REPORTS BEING HIT AND FALLING ON THE LEFT SIDE. AT THE ER, SHE STARTED HAVING SOME CHEST PAIN AND WAS ADMITTED WITH THE ABOVE DIAGNOSIS ON THE MEDICAL FLOOR. SHE WAS ADMITTED FOR PAIN MANAGEMENT, PHYSICAL THERAPY AND OCCUPATIONAL THERAPY.' reason for change: Data Entry Error | (b) (4), (b) (6) | 01 Apr 2021 17:35:23 |
| User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).   | System           | 01 Apr 2021 17:09:42 |
| User entered empty.   | (b) (4), (b) (6) | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 01 Apr 2021 17:09:42 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '0' | System | 01 Apr 2021 17:25:10 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[AEID](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| DataPoint activated with code reason code Data required.      | (b) (4), (b) (6) | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data no required. |                  | 22 Apr 2021 15:01:23 |



US3092245

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:10:08

[Adverse event](#)

| Audit   | User                            | Time (GMT)           |
|---|---------------------------------|----------------------|
| User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0. | Coder Import (b) (4)<br>(b) (4) | 30 Apr 2021 15:58:56 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.  | Coder Import (b) (4)<br>(b) (4) | 30 Apr 2021 15:58:56 |
| Data point term sent to Coder   | System                          | 30 Apr 2021 15:57:44 |
| User entered 'Worsening Overactive Bladder'   | (b) (4), (b) (6)                | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.  |                                 | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required.  |                                 | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this a medically-attended AE?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Yes (Y)'   | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this a Solicited Adverse Reaction?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'No (N)'  | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'No (N)'  | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered '15 Dec 2020'                                     | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Start time \(00:00-23:59\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered empty.  | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[AE start date and time \(derived\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered empty.  | System           | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Yes (Y)'   | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |



**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

*If not Ongoing, end date (dd MMM yyyy)*

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered empty.  | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

**End time (00:00-23:59)**

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered empty.  | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[AE End Date and Time \(derived\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered empty.  | System           | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Severity](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Grade 1/Mild (Grade 1/Mild)'                     | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:10:08

[Is the adverse event serious?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'No (N)'  | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered '0'   | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered '0'   | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered '0'   | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |



**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Hospital Admission Date \(dd MMM yyyy\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered empty.  | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered empty.  | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Admitted to ICU?](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered empty.  | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Number of Days in ICU](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered empty.  | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Persistent or significant disability or incapacity](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered '0'   | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:10:08

[Congenital anomaly or birth defect](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered '0'   | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Other medically important event](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered '0'   | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Relationship to investigational product](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Not Related (NOT RELATED)'                       | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |



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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Relationship to Study Procedure](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Not Applicable (NOT APPLICABLE)'                 | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Action taken with investigational product](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Not Applicable (NOT APPLICABLE)'                 | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[None](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered '0'   | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Concomitant Medication](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered '1'   | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Concomitant Procedure](#)

| Audit   | User             | Time (GMT)           |
|---|------------------|----------------------|
| User entered '0'  | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.      |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data no required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Outcome](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.               |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required.         |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered empty.  | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Narrative](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered empty.  | (b) (4), (b) (6) | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       |                  | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |



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**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered '0'   | System           | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'I'   | System           | 30 Apr 2021 15:57:40 |
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

**US3092245**

**Folder: Adverse Events**

**Form: Adverse Events (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6) | 30 Apr 2021 15:55:38 |
| DataPoint inactivated with code reason code Data not required. |                  | 22 Apr 2021 15:01:23 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:10:08

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)         | 03 May 2021 07:31:32 |
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 05 Nov 2020 23:56:37 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)     | 05 Nov 2020 23:59:25 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)     | 05 Nov 2020 23:59:25 |
| Data point term sent to Coder   | System                              | 05 Nov 2020 23:59:02 |
| User entered 'SHINGLES VACCINE'   | Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:58:55 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 05 Nov 2020 23:58:55 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'PROPHYLAXIS' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:58:55 |
|                            | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '1'          | Marissa Cervenka (b) (4) | 05 Nov 2020 23:58:55 |
|                           | (b) (4)                  |                      |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.<br>' (Site from DM).              | (b) (4)<br>(b) (4), (b) (6)         | 10 Feb 2021 08:10:40 |
| Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.<br>' answered with 'changed ' (Site from DM). | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:31:12 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error  | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:30:59 |
| User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.<br>' (Site from DM).              | (b) (4), (b) (6)                    | 17 Dec 2020 02:56:56 |
| User entered 'IU (IU)'  | Marissa Cervenka (b) (4)<br>(b) (4) | 05 Nov 2020 23:58:55 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:08

If dose unit is Other, specify

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                                    | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|  | (b) (4)                  |                      |
| User entered 'injection' reason for change: Data Entry Error | Robert Miranda (b) (4)   | 04 Feb 2021 01:31:49 |
|  | (b) (4)                  |                      |
| User entered 'vaccine' reason for change: Data Entry Error   | Robert Miranda (b) (4)   | 04 Feb 2021 01:30:59 |
|  | (b) (4)                  |                      |
| User entered empty.  | Marissa Cervenka (b) (4) | 05 Nov 2020 23:58:55 |
|  | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Frequency](#)

| Audit                        | User                     | Time (GMT)           |
|------------------------------|--------------------------|----------------------|
| User signature succeeded.    | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                              | (b) (4)                  |                      |
| User entered 'other (OTHER)' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:58:55 |
|                              | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'YEARLY'     | Marissa Cervenka (b) (4) | 05 Nov 2020 23:58:55 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                    | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|  | (b) (4)                  |                      |
| User entered 'Intramuscular (INTRAMUSCULAR)' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:58:55 |
|  | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 05 Nov 2020 23:58:55 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'UN Feb 2020' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:58:55 |
|                            | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Marissa Cervenka (b) (4) | 05 Nov 2020 23:58:55 |
|                           | (b) (4)                  |                      |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 05 Nov 2020 23:58:55 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'UN Feb 2020' | Marissa Cervenka (b) (4) | 05 Nov 2020 23:58:55 |
|                            | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 05 Nov 2020 23:58:55 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 23:58:55 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 23:58:55 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 05 Nov 2020 23:58:55 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| User signature succeeded.   | Valentine Ebuh (b) (4)                     | 23 Feb 2021 03:47:23 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: AGENTS<br>ACTING ON THE RENIN-ANGIOTENSIN<br>SYSTEM, ATC: ACE INHIBITORS,<br>COMBINATIONS, ATC: ACE INHIBITORS AND<br>DIURETICS, PRODUCT:<br>HYDROCHLOROTHIAZIDE; LISINOPRIL,<br>PRODUCTSYNONYM: LISINOPRIL/HCTZ -<br>version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 06 Nov 2020 00:02:25 |
| 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)            | 06 Nov 2020 00:02:25 |
| Data point term sent to Coder   | System                                     | 06 Nov 2020 00:01:11 |
| User entered 'LISINOPRIL/HCTZ'  | Marissa Cervenka (b) (4)<br>(b) (4)        | 06 Nov 2020 00:00:33 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:08

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                           | (b) (4)                  |                      |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit                       | User                     | Time (GMT)           |
|-----------------------------|--------------------------|----------------------|
| User signature succeeded.   | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                             | (b) (4)                  |                      |
| User entered 'HYPERTENSION' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                             | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:08

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '20/12.5'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                           | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:10:08**

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                                | (b) (4)                  |                      |
| User entered 'once daily (QD)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                                | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                            | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                           | (b) (4)                  |                      |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'UN UNK 2015' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                            | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:10:08

Start date completely unknown

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                           | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:10:08**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                           | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:00:33 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 00:00:33 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 00:00:33 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Nov 2020 00:00:33 |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit   | User  | Time (GMT)                                   |
|---|---|--|
| User signature succeeded.   | Valentine Ebuh (b) (4)                        | 23 Feb 2021 03:47:23                         |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: CALCIUM<br>CHANNEL BLOCKERS, ATC: SELECTIVE<br>CALCIUM CHANNEL BLOCKERS WITH<br>MAINLY VASCULAR EFFECTS, ATC:<br>DIHYDROPYRIDINE DERIVATIVES, PRODUCT:<br>AMLODIPINE - version<br>WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4)    | 06 Nov 2020 00:03:24                         |
| 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)               | 06 Nov 2020 00:03:24                         |
| Data point term sent to Coder<br>User entered 'AMLODIPINE'  | System<br>Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:02:16<br>06 Nov 2020 00:01:49 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:08

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit                       | User                     | Time (GMT)           |
|-----------------------------|--------------------------|----------------------|
| User signature succeeded.   | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                             | (b) (4)                  |                      |
| User entered 'HYPERTENSION' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                             | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '10'         | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                           | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:10:08**

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:08

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                                | (b) (4)                  |                      |
| User entered 'once daily (QD)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                                | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                           | (b) (4)                  |                      |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                            | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'UN UNK 2015' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                            | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:10:08**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                           | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:01:49 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 00:01:49 |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 00:01:49 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Nov 2020 00:01:49 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)     | 06 Nov 2020 06:17:44 |
| 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)     | 06 Nov 2020 06:17:44 |
| Data point term sent to Coder   | System                              | 06 Nov 2020 00:03:16 |
| User entered 'GABAPENTIN'   | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:02:55 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:08

[Indication](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|  | (b) (4)                  |                      |
| User entered 'UPPER RIGHT TORSO PAIN<br>SECONDARY TO SHINGLES' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|  | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '600'        | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|                           | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|                           | (b) (4)                  |                      |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                                | (b) (4)                  |                      |
| User entered 'as needed (PRN)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|                                | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

[If frequency is Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|                            | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:10:08

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'UN UNK 2017' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|                            | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|                           | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|                           | (b) (4)                  |                      |



US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:02:55 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:02:55 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:02:55 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:02:55 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE, PRODUCTSYNONYM: SERTRALIN [SERTRALINE] - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)     | 06 Nov 2020 05:44:28 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)     | 06 Nov 2020 05:44:28 |
| Data point term sent to Coder   | System                              | 06 Nov 2020 00:04:17 |
| User entered 'SERTRALIN'  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:03:49 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'DEPRESSION' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '100'        | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                           | (b) (4)                  |                      |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

[If dose unit is Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                                | (b) (4)                  |                      |
| User entered 'once daily (QD)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                                | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                            | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'UN UNK 2017' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                            | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                           | (b) (4)                  |                      |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:10:08

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:03:49 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 00:03:49 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 00:03:49 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Nov 2020 00:03:49 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)                     | 23 Feb 2021 03:47:23 |
| User coded data point as ATC: SENSORY<br>ORGANS, ATC: OPHTHALMOLOGICALS, ATC:<br>ANTIGLAUCOMA PREPARATIONS AND<br>MIOTICS, ATC: PROSTAGLANDIN<br>ANALOGUES, PRODUCT: TRAVOPROST,<br>PRODUCTSYNONYM: TRAVATAN - version<br>WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 06 Nov 2020 05:39:29 |
| 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 Nov 2020 05:39:29 |
| Data point term sent to Coder  | System                                     | 06 Nov 2020 00:17:39 |
| User entered 'TRAVATIN'  | Marissa Cervenka (b) (4)<br>(b) (4)        | 06 Nov 2020 00:16:47 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:16:47 |
|                           | (b) (4)                  |                      |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'GLAUCOMA'   | Marissa Cervenka (b) (4) | 06 Nov 2020 00:16:47 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:08

[Dose per administration](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User closed query 'Per DM CLR: Please note, 0.04 mg pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of drops (e.g., Dose=1, If dose unit is Other, specify = drop) would be more appropriate recording. If so, update eCRF as appropriate. ' (Site from DM).              | (b) (4)<br>(b) (4), (b) (6)         | 10 Feb 2021 08:11:09 |
| Query 'Per DM CLR: Please note, 0.04 mg pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of drops (e.g., Dose=1, If dose unit is Other, specify = drop) would be more appropriate recording. If so, update eCRF as appropriate. ' answered with 'changed ' (Site from DM). | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:33:20 |
| User entered '1' reason for change: Data Entry Error   | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:33:10 |
| User opened query 'Per DM CLR: Please note, 0.04 mg pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of drops (e.g., Dose=1, If dose unit is Other, specify = drop) would be more appropriate recording. If so, update eCRF as appropriate. ' (Site from DM).              | (b) (4), (b) (6)                    | 17 Dec 2020 02:58:09 |
| User entered '0.04'  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:16:47 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.                       | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|   | (b) (4)                  |                      |
| User entered 'Other (OTHER)' reason for change: | Robert Miranda (b) (4)   | 04 Feb 2021 01:33:10 |
| Data Entry Error                                | (b) (4)                  |                      |
| User entered 'mg (mg)'                          | Marissa Cervenka (b) (4) | 06 Nov 2020 00:16:47 |
|   | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:08

If dose unit is Other, specify

| Audit   | User                     | Time (GMT)           |
|---|--------------------------|----------------------|
| User signature succeeded.                               | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|   | (b) (4)                  |                      |
| User entered 'drop' reason for change: Data Entry Error | Robert Miranda (b) (4)   | 04 Feb 2021 01:33:10 |
|   | (b) (4)                  |                      |
| User entered empty.                                     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:16:47 |
|   | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:08

[Frequency](#)

| Audit                            | User                     | Time (GMT)           |
|----------------------------------|--------------------------|----------------------|
| User signature succeeded.        | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                                  | (b) (4)                  |                      |
| User entered 'unknown (UNKNOWN)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:16:47 |
|                                  | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:10:08**

[If frequency is Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:16:47 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                                    | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|  | (b) (4)                  |                      |
| User entered 'Intraocular (INTRAOCULAR)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:16:47 |
|  | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:16:47 |
|                           | (b) (4)                  |                      |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'UN UNK 2017' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:16:47 |
|                            | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Marissa Cervenka (b) (4) | 06 Nov 2020 00:16:47 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:16:47 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:10:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:16:47 |
|                           | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:16:47 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:16:47 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:16:47 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:16:47 |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)                     | 23 Feb 2021 03:47:23 |
| User coded data point as ATC:<br>CARDIOVASCULAR SYSTEM, ATC: LIPID<br>MODIFYING AGENTS, ATC: LIPID MODIFYING<br>AGENTS, PLAIN, ATC: HMG COA REDUCTASE<br>INHIBITORS, PRODUCT: ATORVASTATIN -<br>version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 06 Nov 2020 00:19:24 |
| 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)            | 06 Nov 2020 00:19:24 |
| Data point term sent to Coder  | System                                     | 06 Nov 2020 00:18:40 |
| User entered 'ATORVASTATIN'  | Marissa Cervenka (b) (4)<br>(b) (4)        | 06 Nov 2020 00:18:29 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:08

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:08

[Indication](#)

| Audit                               | User                                | Time (GMT)           |
|-------------------------------------|-------------------------------------|----------------------|
| User signature succeeded.           | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User entered 'HYPERCHOLESTEROLEMIA' | (b) (4)<br>Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '40'         | Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:10:08**

[If dose unit is Other, specify](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                                | (b) (4)                  |                      |
| User entered 'once daily (QD)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |
|                                | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |
|                           | (b) (4)                  |                      |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |
|                            | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:08

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'UN UNK 2017' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |
|                            | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:10:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |
|                           | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:18:29 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 00:18:29 |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered '1' | System | 06 Nov 2020 00:18:29 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 06 Nov 2020 00:18:29 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)                     | 23 Feb 2021 03:47:23 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN -<br>version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 06 Nov 2020 01:23:26 |
| 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 Nov 2020 01:23:26 |
| Data point term sent to Coder  | System                                     | 06 Nov 2020 00:22:44 |
| User entered 'IBUPROFEN'   | Marissa Cervenka (b) (4)<br>(b) (4)        | 06 Nov 2020 00:22:10 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:08

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit  | User                     | Time (GMT)           |
|--|--------------------------|----------------------|
| User signature succeeded.                    | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|  | (b) (4)                  |                      |
| User entered 'BILATERAL KNEE AND ANKLE PAIN' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|  | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:08

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '400'        | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:08

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|                           | (b) (4)                  |                      |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                                | (b) (4)                  |                      |
| User entered 'as needed (PRN)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|                                | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|                            | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'UN UNK 2015' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|                            | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:10:08**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|                           | (b) (4)                  |                      |



US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:22:10 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:22:10 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:22:10 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:22:10 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit  | User  | Time (GMT)                                   |
|--|---|--|
| User signature succeeded.  | Valentine Ebuh (b) (4)                        | 23 Feb 2021 03:47:23                         |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: NAPROXEN<br>SODIUM, PRODUCTSYNONYM: ALEVE -<br>version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4)    | 06 Nov 2020 00:25:32                         |
| 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)               | 06 Nov 2020 00:25:32                         |
| Data point term sent to Coder<br>User entered 'ALEVE'  | System<br>Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:24:45<br>06 Nov 2020 00:24:09 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:10:08

[Prophylaxis](#)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).               | (b) (4)<br>(b) (4), (b) (6)         | 02 Feb 2021 06:06:20 |
| Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'corrected' (Site from DM). | (b) (4), (b) (6)                    | 27 Jan 2021 20:18:50 |
| User entered 'No (N)' reason for change: Data Entry Error   |                                     | 27 Jan 2021 20:18:41 |
| User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).               |                                     | 17 Dec 2020 02:58:29 |
| User entered 'Yes (Y)'  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:24:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit                              | User                     | Time (GMT)           |
|------------------------------------|--------------------------|----------------------|
| User signature succeeded.          | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                                    | (b) (4)                  |                      |
| User entered 'BILATERAL KNEE PAIN' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:24:09 |
|                                    | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '220'        | Marissa Cervenka (b) (4) | 06 Nov 2020 00:24:09 |
|                           | (b) (4)                  |                      |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:24:09 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:10:08

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:24:09 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                                | (b) (4)                  |                      |
| User entered 'as needed (PRN)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:24:09 |
|                                | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:24:09 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:24:09 |
|                            | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:24:09 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:10:08

Start date (dd MMM yyyy)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'UN UNK 2015' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:24:09 |
|                            | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Marissa Cervenka (b) (4) | 06 Nov 2020 00:24:09 |
|                           | (b) (4)                  |                      |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'Yes (Y)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:24:09 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:10:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:24:09 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:10:08

[Was this medication taken for solicited event?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:24:09 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:24:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:24:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:24:09 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

Name of Medication

| Audit  | User  | Time (GMT)                                   |
|--|---|--|
| User signature succeeded.  | Valentine Ebuh (b) (4)                        | 05 Apr 2021 02:38:58                         |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN -<br>version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4)    | 31 Mar 2021 23:15:05                         |
| 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)               | 31 Mar 2021 23:15:05                         |
| Data point term sent to Coder<br>DataPoint activated with code reason code Data<br>required.   | System<br>(b) (4), (b) (6)                    | 31 Mar 2021 23:14:43<br>31 Mar 2021 23:14:15 |
| Data point term sent to Coder<br>DataPoint inactivated with code reason code Data not<br>required.   | System<br>Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:55<br>04 Feb 2021 01:34:21 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STEROIDS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: IBUPROFEN -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 06 Nov 2020 01:24:31                         |
| 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 Nov 2020 01:24:31                         |
| Data point term sent to Coder<br>User entered 'IBUPROFEN'  | System<br>Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:56<br>06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

[Prophylaxis](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:21 |
| User entered 'No (N)'  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:21 |
| User entered 'BODY/MUSCLE ACHES'                               | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

[Dose per administration](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:21 |
| User entered '400'   | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:21 |
| User entered 'mg (mg)'   | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

If dose unit is Other, specify

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:21 |
| User entered empty.  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

[Frequency](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:21 |
| User entered 'as needed (PRN)'                                 | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:21 |
| User entered empty.  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

[Route of administration](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:21 |
| User entered 'Oral (ORAL)'                                     | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

If route of administration is Other, specify

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:21 |
| User entered empty.  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

Start date (dd MMM yyyy)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 8. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.' (Site from DM).   | (b) (4), (b) (6)                    | 07 Apr 2021 19:38:12 |
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 8. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.' answered with 'Original start/stop date of this medication for this indication of body/muscle aches is correct. This Con Med was taken for an indication regarding an adverse reaction, whereas Con Med 8 was taken for an ongoing medical history indication of bilateral knee and ankle pain. Thus, this medication was taken for multiple indications, but was stopped for Body/Muscle Aches since this was a solicited symptom that only lasted 5 days' (Site from DM). | (b) (4)<br>(b) (4), (b) (6)         | 01 Apr 2021 15:22:41 |
| User entered '30 Sep 2020' reason for change: Data Entry Error  | (b) (4), (b) (6)                    | 01 Apr 2021 15:03:33 |
| DataPoint activated with code reason code Data required.  |                                     | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required.  | Robert Miranda (b) (4)              | 04 Feb 2021 01:34:21 |
| User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 8. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)         | 17 Dec 2020 03:01:02 |
| User entered '3 Sep 2020'   | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

[Start date completely unknown](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:21 |
| User entered '0'   | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

[Ongoing?](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.                               | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required.                         | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:21 |
| User closed query 'Data is required. Please complete.' (Site from System).             | System                              | 06 Nov 2020 00:33:21 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System                              | 06 Nov 2020 00:33:21 |
| User entered 'No (N)' reason for change: Data Entry Error                              | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:21 |
| User opened query 'Data is required. Please complete.' (Site from System).             | System                              | 06 Nov 2020 00:33:06 |
| User entered empty.  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:21 |
| User entered '4 Oct 2020'                                      | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

[Was this medication taken for solicited event?](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:21 |
| User entered 'Yes (Y)'   | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

[Separate Dosage Number \(derived\)](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)       | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4) | 04 Feb 2021 01:34:21 |
| User entered empty.  | System                 | 06 Nov 2020 00:33:06 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)       | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4) | 04 Feb 2021 01:34:21 |
| User entered empty.  | System                 | 06 Nov 2020 00:33:06 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:10:08

[Interval Dosage Definition \(derived\)](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)       | 31 Mar 2021 23:14:15 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4) | 04 Feb 2021 01:34:21 |
| User entered empty.  | System                 | 06 Nov 2020 00:33:06 |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

Name of Medication

| Audit  | User  | Time (GMT)                                   |
|--|---|--|
| User signature succeeded.  | Valentine Ebuh (b) (4)                        | 05 Apr 2021 02:38:58                         |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STERIODS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: NAPROXEN<br>SODIUM, PRODUCTSYNONYM: ALEVE -<br>version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4)    | 31 Mar 2021 23:16:06                         |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)               | 31 Mar 2021 23:16:06                         |
| Data point term sent to Coder<br>DataPoint activated with code reason code Data<br>required.   | System<br>(b) (4), (b) (6)                    | 31 Mar 2021 23:15:44<br>31 Mar 2021 23:14:46 |
| Data point term sent to Coder<br>DataPoint inactivated with code reason code Data not<br>required.   | System<br>Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:54<br>04 Feb 2021 01:34:50 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC:<br>ANTIINFLAMMATORY AND ANTIRHEUMATIC<br>PRODUCTS, ATC: ANTIINFLAMMATORY AND<br>ANTIRHEUMATIC PRODUCTS,<br>NON-STERIODS, ATC: PROPIONIC ACID<br>DERIVATIVES, PRODUCT: NAPROXEN<br>SODIUM, PRODUCTSYNONYM: ALEVE -<br>version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)               | 06 Nov 2020 06:27:35                         |
| 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 Nov 2020 06:27:35                         |
| Data point term sent to Coder<br>User entered 'ALEVE'  | System<br>Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:57<br>06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

[Prophylaxis](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:50 |
| User entered 'No (N)'  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

[Indication](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:50 |
| User entered 'BODY/MUSCLE ACHES'                               | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

[Dose per administration](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:50 |
| User entered '220'   | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:50 |
| User entered 'mg (mg)'   | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

If dose unit is Other, specify

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:50 |
| User entered empty.  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

[Frequency](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:50 |
| User entered 'as needed (PRN)'                                 | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:50 |
| User entered empty.  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

[Route of administration](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:50 |
| User entered 'Oral (ORAL)'                                     | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

If route of administration is Other, specify

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:50 |
| User entered empty.  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

Start date (dd MMM yyyy)

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 9. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.<br>' (Site from DM).   | (b) (4), (b) (6)                    | 06 Apr 2021 10:01:45 |
| User signature succeeded.   | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 9. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.<br>' answered with 'The start/stop date of this medication for body/muscle aches is correct. This Con Med was taken for an indication regarding an adverse reaction, whereas Con Med 9 was taken for an ongoing medical history indication of bilateral knee and ankle pain. Thus, this medication was taken for multiple indications, but was stopped for Body/Muscle Aches since this was a solicited symptom that only lasted 5 days' (Site from DM). | (b) (4)<br>(b) (4), (b) (6)         | 01 Apr 2021 15:26:07 |
| User entered '30 Sep 2020' reason for change: Data Entry Error  | (b) (4), (b) (6)                    | 01 Apr 2021 15:23:46 |
| DataPoint activated with code reason code Data required.  |                                     | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required.  | Robert Miranda (b) (4)              | 04 Feb 2021 01:34:50 |
| User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 9. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate.<br>' (Site from DM).   | (b) (4)<br>(b) (4), (b) (6)         | 17 Dec 2020 03:01:41 |
| User entered '3 Sep 2020'   | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

[Start date completely unknown](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:50 |
| User entered '0'   | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

[Ongoing?](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:50 |
| User entered 'No (N)'  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:50 |
| User entered '4 Oct 2020'                                      | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

[Was this medication taken for solicited event?](#)

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)              | 05 Apr 2021 02:38:58 |
| DataPoint activated with code reason code Data required.       | (b) (4)<br>(b) (4), (b) (6)         | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4)<br>(b) (4)   | 04 Feb 2021 01:34:50 |
| User entered 'Yes (Y)'   | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

[Separate Dosage Number \(derived\)](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)       | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4) | 04 Feb 2021 01:34:50 |
| User entered empty.  | System                 | 06 Nov 2020 00:36:53 |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)       | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4) | 04 Feb 2021 01:34:50 |
| User entered empty.  | System                 | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:10:08

[Interval Dosage Definition \(derived\)](#)

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| DataPoint activated with code reason code Data required.       | (b) (4), (b) (6)       | 31 Mar 2021 23:14:46 |
| DataPoint inactivated with code reason code Data not required. | Robert Miranda (b) (4) | 04 Feb 2021 01:34:50 |
| User entered empty.  | System                 | 06 Nov 2020 00:36:53 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:08

Name of Medication

| Audit  | User                                | Time (GMT)           |
|--|-------------------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)              | 23 Feb 2021 03:47:23 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)     | 06 Nov 2020 00:40:27 |
| 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)     | 06 Nov 2020 00:40:27 |
| Data point term sent to Coder  | System                              | 06 Nov 2020 00:38:59 |
| User entered 'TYLENOL'   | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:38:08 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Prophylaxis](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:38:08 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:08

[Indication](#)

| Audit                           | User                     | Time (GMT)           |
|---------------------------------|--------------------------|----------------------|
| User signature succeeded.       | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                                 | (b) (4)                  |                      |
| User entered 'BODY/MUSCLE ACHE' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:38:08 |
|                                 | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:08

[Dose per administration](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '500'        | Marissa Cervenka (b) (4) | 06 Nov 2020 00:38:08 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'mg (mg)'    | Marissa Cervenka (b) (4) | 06 Nov 2020 00:38:08 |
|                           | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:10:08**

If dose unit is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:38:08 |
|                           | (b) (4)                  |                      |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Frequency](#)

| Audit                          | User                     | Time (GMT)           |
|--------------------------------|--------------------------|----------------------|
| User signature succeeded.      | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                                | (b) (4)                  |                      |
| User entered 'as needed (PRN)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:38:08 |
|                                | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:38:08 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                     | Time (GMT)           |
|----------------------------|--------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                            | (b) (4)                  |                      |
| User entered 'Oral (ORAL)' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:38:08 |
|                            | (b) (4)                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered empty.       | Marissa Cervenka (b) (4) | 06 Nov 2020 00:38:08 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:08

Start date (dd MMM yyyy)

| Audit  | User   | Time (GMT)           |
|--|--|----------------------|
| User signature succeeded.                                      | Valentine Ebuh (b) (4)                         | 28 Mar 2021 01:06:13 |
| Signature has been broken.                                     | (b) (4)<br>(b) (4), (b) (6)                    | 12 Mar 2021 01:02:53 |
| User entered '30 Sep 2020' reason for change: Data Entry Error |  | 12 Mar 2021 01:02:53 |
| User signature succeeded.                                      | Valentine Ebuh (b) (4)                         | 23 Feb 2021 03:47:23 |
| User entered '3 Sep 2020'                                      | (b) (4)<br>Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:38:08 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '0'          | Marissa Cervenka (b) (4) | 06 Nov 2020 00:38:08 |
|                           | (b) (4)                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered 'No (N)'     | Marissa Cervenka (b) (4) | 06 Nov 2020 00:38:08 |
|                           | (b) (4)                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                     | User                     | Time (GMT)           |
|---------------------------|--------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)   | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                  |                      |
| User entered '4 Oct 2020' | Marissa Cervenka (b) (4) | 06 Nov 2020 00:38:08 |
|                           | (b) (4)                  |                      |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:10:08

Was this medication taken for solicited event?

| Audit   | User                                | Time (GMT)           |
|---|-------------------------------------|----------------------|
| User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of BODY/MUSCLE ACHE in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' (Site from DM).  | (b) (4), (b) (6)                    | 31 Mar 2021 02:08:49 |
| Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of BODY/MUSCLE ACHE in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' answered with 'I called the subject. The Tylenol was used for solicited AE. The subject said that she might have not recorded it in her diary. ' (Site from DM). | Valentine Ebuh (b) (4)<br>(b) (4)   | 26 Mar 2021 15:50:26 |
| User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of BODY/MUSCLE ACHE in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' (Site from DM).  | (b) (4), (b) (6)                    | 22 Mar 2021 04:39:49 |
| User signature succeeded.   | Valentine Ebuh (b) (4)<br>(b) (4)   | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'  | Marissa Cervenka (b) (4)<br>(b) (4) | 06 Nov 2020 00:38:08 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:38:08 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:38:08 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 06 Nov 2020 00:38:08 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:08

Name of Medication

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| DataPoint Verified.  | (b) (4), (b) (6)                           | 20 Apr 2021 20:23:24 |
| User signature succeeded.  | Valentine Ebuh (b) (4)                     | 23 Feb 2021 03:47:23 |
| User coded data point as ATC: NERVOUS<br>SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS,<br>ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL<br>- version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 28 Jan 2021 13:28:18 |
| 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)            | 28 Jan 2021 13:28:18 |
| Data point term sent to Coder  | System                                     | 27 Jan 2021 20:27:59 |
| User entered 'tramadol'  | (b) (4), (b) (6)                           | 27 Jan 2021 20:27:32 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:23:26 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit                                 | User                        | Time (GMT)           |
|---------------------------------------|-----------------------------|----------------------|
| DataPoint Verified.                   | (b) (4), (b) (6)            | 20 Apr 2021 20:23:34 |
| User signature succeeded.             | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'motor vehicle accident' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:08

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:23:36 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'unknown'    | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Dose unit](#)

| Audit                        | User                        | Time (GMT)           |
|------------------------------|-----------------------------|----------------------|
| DataPoint Verified.          | (b) (4), (b) (6)            | 20 Apr 2021 20:23:38 |
| User signature succeeded.    | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Other (OTHER)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:23:39 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'unknown'    | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| DataPoint Verified.            | (b) (4), (b) (6)            | 20 Apr 2021 20:23:42 |
| User signature succeeded.      | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'as needed (PRN)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:25:30 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 20 Apr 2021 20:25:32 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:08

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:25:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)            | 20 Apr 2021 20:25:35 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '01 Dec 2020' | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:25:51 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:25:53 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

**If not Ongoing, End date (*dd MMM yyyy*)**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:25:55 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:10:08

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:25:57 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 27 Jan 2021 20:27:32 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Jan 2021 20:27:32 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Jan 2021 20:27:32 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 27 Jan 2021 20:27:32 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                           | 01 May 2021 14:08:43 |
| User signature succeeded.   | Valentine Ebuh (b) (4)                     | 28 Mar 2021 01:06:13 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 08 Mar 2021 15:55:39 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)            | 08 Mar 2021 15:55:39 |
| Data point term sent to Coder   | System                                     | 08 Mar 2021 15:54:26 |
| User entered 'Oxybutynin'   | Catina Adams (b) (4)<br>(b) (4)            | 08 Mar 2021 15:53:27 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:10:08**

[Prophylaxis](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 14:08:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 01:06:13 |
| User entered 'No (N)'     | Catina Adams (b) (4)   | 08 Mar 2021 15:53:27 |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit                             | User                   | Time (GMT)           |
|-----------------------------------|------------------------|----------------------|
| Data hard locked.                 | (b) (4), (b) (6)       | 01 May 2021 14:08:43 |
| User signature succeeded.         | Valentine Ebuh (b) (4) | 28 Mar 2021 01:06:13 |
| User entered 'Overactive Bladder' | Catina Adams (b) (4)   | 08 Mar 2021 15:53:27 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:08

[Dose per administration](#)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.                                    | (b) (4), (b) (6)                           | 01 May 2021 14:08:43 |
| User signature succeeded.                            | Valentine Ebuh (b) (4)                     | 14 Apr 2021 01:03:51 |
| Signature has been broken.                           | (b) (4)<br>(b) (4), (b) (6)                | 05 Apr 2021 12:49:04 |
| User entered '5' reason for change: Data Entry Error |  | 05 Apr 2021 12:49:04 |
| User signature succeeded.                            | Valentine Ebuh (b) (4)                     | 28 Mar 2021 01:06:13 |
| User entered '30'                                    | (b) (4)<br>Catina Adams (b) (4)<br>(b) (4) | 08 Mar 2021 15:53:27 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 14:08:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 01:06:13 |
| User entered 'mg (mg)'    | Catina Adams (b) (4)   | 08 Mar 2021 15:53:27 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:08

If dose unit is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 14:08:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 01:06:13 |
| User entered empty.       | Catina Adams (b) (4)   | 08 Mar 2021 15:53:27 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:08

[Frequency](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                           | 01 May 2021 14:08:43 |
| User signature succeeded.   | Valentine Ebuh (b) (4)                     | 29 Apr 2021 02:23:41 |
| Signature has been broken.  | (b) (4)<br>(b) (4), (b) (6)                | 20 Apr 2021 19:23:59 |
| User entered 'twice daily (BID)' reason for change:<br>Data Entry Error |  | 20 Apr 2021 19:23:59 |
| User signature succeeded.   | Valentine Ebuh (b) (4)                     | 28 Mar 2021 01:06:13 |
| User entered 'once daily (QD)'  | (b) (4)<br>Catina Adams (b) (4)<br>(b) (4) | 08 Mar 2021 15:53:27 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 14:08:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 01:06:13 |
| User entered empty.       | Catina Adams (b) (4)   | 08 Mar 2021 15:53:27 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)       | 01 May 2021 14:08:43 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 28 Mar 2021 01:06:13 |
| User entered 'Oral (ORAL)' | Catina Adams (b) (4)   | 08 Mar 2021 15:53:27 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:08

If route of administration is Other, specify

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 14:08:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 01:06:13 |
| User entered empty.       | Catina Adams (b) (4)   | 08 Mar 2021 15:53:27 |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:08

Start date (dd MMM yyyy)

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6)       | 01 May 2021 14:08:43 |
| User signature succeeded.   | Valentine Ebuh (b) (4) | 28 Mar 2021 01:06:13 |
| User closed query 'Future date has been entered. Please correct.' (Site from System). | (b) (4)                |                      |
| User entered '20 Jun 2020' reason for change: Data Entry Error                        | System                 | 08 Mar 2021 15:53:36 |
| User opened query 'Future date has been entered. Please correct.' (Site from System). | Catina Adams (b) (4)   | 08 Mar 2021 15:53:36 |
| User entered '20 Jun 2021'  | (b) (4)                |                      |
|   | System                 | 08 Mar 2021 15:53:27 |
|   | Catina Adams (b) (4)   | 08 Mar 2021 15:53:27 |
|   | (b) (4)                |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 14:08:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 01:06:13 |
| User entered '0'          | Catina Adams (b) (4)   | 08 Mar 2021 15:53:27 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:08

[Ongoing?](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                           | 01 May 2021 14:08:43 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)                     | 29 Apr 2021 02:23:41 |
| Signature has been broken.                                | (b) (4)<br>(b) (4), (b) (6)                | 20 Apr 2021 19:23:59 |
| User entered 'No (N)' reason for change: Data Entry Error |  | 20 Apr 2021 19:23:59 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)                     | 28 Mar 2021 01:06:13 |
| User entered 'Yes (Y)'                                    | (b) (4)<br>Catina Adams (b) (4)<br>(b) (4) | 08 Mar 2021 15:53:27 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit  | User                                       | Time (GMT)           |
|--|--|----------------------|
| Data hard locked.  | (b) (4), (b) (6)                           | 01 May 2021 14:08:43 |
| User signature succeeded.                                      | Valentine Ebuh (b) (4)                     | 29 Apr 2021 02:23:41 |
| Signature has been broken.                                     | (b) (4)<br>(b) (4), (b) (6)                | 20 Apr 2021 19:23:59 |
| User entered '09 Mar 2021' reason for change: Data Entry Error |  | 20 Apr 2021 19:23:59 |
| User signature succeeded.                                      | Valentine Ebuh (b) (4)                     | 28 Mar 2021 01:06:13 |
| User entered empty.  | (b) (4)<br>Catina Adams (b) (4)<br>(b) (4) | 08 Mar 2021 15:53:27 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:08

[Was this medication taken for solicited event?](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)       | 01 May 2021 14:08:43 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 28 Mar 2021 01:06:13 |
| User entered 'No (N)'     | Catina Adams (b) (4)   | 08 Mar 2021 15:53:27 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:08:43 |
| User entered '2'  | System           | 20 Apr 2021 19:23:59 |
| User entered '1'  | System           | 08 Mar 2021 15:53:27 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:10:08

[Interval Dosage Unit Number \(derived\)](#)

| Audit             | User             | Time (GMT)           |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:08:43 |
| User entered '1'  | System           | 08 Mar 2021 15:53:27 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User             | Time (GMT)           |
|--------------------------|------------------|----------------------|
| Data hard locked.        | (b) (4), (b) (6) | 01 May 2021 14:08:43 |
| User entered '804 (804)' | System           | 08 Mar 2021 15:53:27 |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)          | 28 Mar 2021 01:06:13 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 12 Mar 2021 01:18:56 |
| 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) | 12 Mar 2021 01:18:56 |
| Data point term sent to Coder  | System                          | 12 Mar 2021 01:18:27 |
| User entered 'Tylenol'   | (b) (4), (b) (6)                | 12 Mar 2021 01:17:34 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                        | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'back knee pain<br>back ankle pain' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered '500'        | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

[If dose unit is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'as needed (PRN)' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'un UNK 2015' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:17:34 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Mar 2021 01:17:34 |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Mar 2021 01:17:34 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 12 Mar 2021 01:17:34 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit  | User                            | Time (GMT)           |
|--|---------------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)          | 28 Mar 2021 01:06:13 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4) | 12 Mar 2021 01:33:00 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4) | 12 Mar 2021 01:33:00 |
| Data point term sent to Coder  | System                          | 12 Mar 2021 01:24:28 |
| User entered 'amitriptyline'   | (b) (4), (b) (6)                | 12 Mar 2021 01:23:59 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:10:08**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'sleep aide from mva due to pain left upper and lower extremities & LBP' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:08

[Dose per administration](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.                             | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| Signature has been broken.                            | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:22:32 |
| User entered '25' reason for change: Data Entry Error |                             | 20 Apr 2021 19:22:32 |
| User signature succeeded.                             | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered '5'                                      | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:08

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:08

[Frequency](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| Signature has been broken.  | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:22:32 |
| User entered 'as needed (PRN)' reason for change:<br>Data Entry Error |                             | 20 Apr 2021 19:22:32 |
| User signature succeeded.   | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'once daily (QD)'  | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered '19 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:10:08**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:23:59 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Apr 2021 19:22:32 |
| User entered '1'    | System | 12 Mar 2021 01:23:59 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Apr 2021 19:22:32 |
| User entered '1'    | System | 12 Mar 2021 01:23:59 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit                    | User   | Time (GMT)           |
|--------------------------|--------|----------------------|
| User entered empty.      | System | 20 Apr 2021 19:22:32 |
| User entered '804 (804)' | System | 12 Mar 2021 01:23:59 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit   | User                                       | Time (GMT)           |
|---|--|----------------------|
| Data hard locked.   | (b) (4), (b) (6)                           | 01 May 2021 14:08:29 |
| User signature succeeded.   | Valentine Ebuh (b) (4)                     | 28 Mar 2021 01:06:13 |
| User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL W/CODEINE NO. 3 - version WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 16 Mar 2021 15:08:53 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)            | 16 Mar 2021 15:08:53 |
| Data point term sent to Coder   | System                                     | 12 Mar 2021 01:28:31 |
| User entered 'TYLENOL 3 (CODEINE/ACETAMINOPHEN)'  | (b) (4), (b) (6)                           | 12 Mar 2021 01:28:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| Data hard locked.                               | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded.                       | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'SECONDARY/MOTOR VEHICLE ACCIDENT' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered '300'        | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:08

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| Data hard locked.              | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded.      | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'as needed (PRN)' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:08

If frequency is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:10:08

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered '01 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered '14 Jan 2021' | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 14:08:29 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 01:28:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 14:08:29 |
| User entered empty. | System           | 12 Mar 2021 01:28:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 14:08:29 |
| User entered empty. | System           | 12 Mar 2021 01:28:09 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| Data hard locked.   | (b) (4), (b) (6) | 01 May 2021 14:08:29 |
| User entered empty. | System           | 12 Mar 2021 01:28:09 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit   | User                                       | Time (GMT)                                   |
|---|--|--|
| User signature succeeded.   | Valentine Ebuh (b) (4)                     | 29 Apr 2021 02:23:41                         |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE<br>RELAXANTS, ATC: MUSCLE RELAXANTS,<br>CENTRALLY ACTING AGENTS, ATC: OTHER<br>CENTRALLY ACTING AGENTS, PRODUCT:<br>CYCLOBENZAPRINE - version<br>WHODrug-Global-B3\\202003. | (b) (4)<br>Coder Import (b) (4)<br>(b) (4) | 20 Apr 2021 19:41:39                         |
| User coded data point as Term Coded data point by<br>User: (b) (6) - version<br>WHODrug-Global-B3\\202003.  | Coder Import (b) (4)<br>(b) (4)            | 20 Apr 2021 19:41:39                         |
| Data point term sent to Coder<br>Coding entries removed.  | System<br>(b) (4), (b) (6)                 | 20 Apr 2021 19:21:00<br>20 Apr 2021 19:20:07 |
| User coded data point as ATC:<br>MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE<br>RELAXANTS, ATC: MUSCLE RELAXANTS,<br>CENTRALLY ACTING AGENTS, ATC: OTHER<br>CENTRALLY ACTING AGENTS, PRODUCT:<br>CYCLOBENZAPRINE - version<br>WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)            | 20 Apr 2021 19:12:31                         |
| User coded data point as Term Coded data point by<br>User: Coder System - version<br>WHODrug-Global-B3\\202003.   | Coder Import (b) (4)<br>(b) (4)            | 20 Apr 2021 19:12:31                         |
| Data point term sent to Coder<br>User entered 'CYCLOBENZAPRINE'   | System<br>(b) (4), (b) (6)                 | 20 Apr 2021 19:11:26<br>20 Apr 2021 19:11:19 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

[Prophylaxis](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:11:19 |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:08

[Indication](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| User signature succeeded.   | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered 'MUSCLE SPASMS BILATERAL LEGS' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:20:07 |
| User entered 'MUSCLE SPASMS'  |                             | 20 Apr 2021 19:11:19 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

[Dose per administration](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered '10'         | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:11:19 |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:10:08

[Dose unit](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered 'mg (mg)'    | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:11:19 |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

If dose unit is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:11:19 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

[Frequency](#)

| Audit                          | User                        | Time (GMT)           |
|--------------------------------|-----------------------------|----------------------|
| User signature succeeded.      | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered 'as needed (PRN)' | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:11:19 |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

[If frequency is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:11:19 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered 'Oral (ORAL)' | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:11:19 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:11:19 |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date \(dd MMM yyyy\)](#)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered 'UN Jun 2020' | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:11:19 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered '0'          | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:11:19 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered 'Yes (Y)'    | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:11:19 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

*If not Ongoing, End date (dd MMM yyyy)*

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:11:19 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this medication taken for solicited event?](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered 'No (N)'     | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 19:11:19 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Apr 2021 19:11:19 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Apr 2021 19:11:19 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 20 Apr 2021 19:11:19 |



US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:08

[Name of Medication](#)

| Audit  | User                                 | Time (GMT)           |
|--|--------------------------------------|----------------------|
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: STEROIDS - version WHODrug-Global-B3\\202003. | Coder Import (b) (4)<br>(b) (4)      | 30 Apr 2021 17:51:05 |
| 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 Apr 2021 17:51:05 |
| Data point term sent to Coder  | System                               | 30 Apr 2021 16:09:08 |
| User entered 'EPIDURAL STERIOD INJECTION'  | (b) (4), (b) (6)<br>(b) (4), (b) (6) | 30 Apr 2021 16:09:06 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

[Prophylaxis](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |
|                       |                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'OBESITY' | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |
|                        |                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

[Dose per administration](#)

| Audit              | User             | Time (GMT)           |
|--------------------|------------------|----------------------|
| User entered 'UNK' | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |
|                    |                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

[Dose unit](#)

| Audit                        | User             | Time (GMT)           |
|------------------------------|------------------|----------------------|
| User entered 'Other (OTHER)' | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |
|                              |                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

[If dose unit is Other, specify](#)

| Audit                  | User             | Time (GMT)           |
|------------------------|------------------|----------------------|
| User entered 'UNKNOWN' | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |
|                        |                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:08

[Frequency](#)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered 'once (ONCE)' | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |
|                            |                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

[If frequency is Other, specify](#)

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |
|                     |                  |                      |



US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

[Route of administration](#)

| Audit  | User             | Time (GMT)           |
|--|------------------|----------------------|
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

If route of administration is Other, specify

| Audit               | User             | Time (GMT)           |
|---------------------|------------------|----------------------|
| User entered empty. | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |
|                     |                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:08

Start date (*dd MMM yyyy*)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '27 Apr 2021' | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |
|                            |                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

[Start date completely unknown](#)

| Audit            | User             | Time (GMT)           |
|------------------|------------------|----------------------|
| User entered '0' | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |
|                  |                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

[Ongoing?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |
|                       |                  |                      |

US3092245

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:10:08

If not Ongoing, End date (*dd MMM yyyy*)

| Audit                      | User             | Time (GMT)           |
|----------------------------|------------------|----------------------|
| User entered '27 Apr 2021' | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |
|                            |                  |                      |

US3092245

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

[Was this medication taken for solicited event?](#)

| Audit                 | User             | Time (GMT)           |
|-----------------------|------------------|----------------------|
| User entered 'No (N)' | (b) (4), (b) (6) | 30 Apr 2021 16:09:06 |
|                       |                  |                      |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

[Separate Dosage Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Apr 2021 16:09:06 |



**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Unit Number \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Apr 2021 16:09:06 |

**US3092245**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:10:08**

[Interval Dosage Definition \(derived\)](#)

| Audit               | User   | Time (GMT)           |
|---------------------|--------|----------------------|
| User entered empty. | System | 30 Apr 2021 16:09:06 |

US3092245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:10:08

[Were any concomitant procedures performed?](#)

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| Data hard locked.  | (b) (4), (b) (6)            | 03 May 2021 07:31:32 |
| User signature succeeded.                                  | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Signature has been broken.                                 | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 22:59:55 |
| User entered 'Yes (Y)' reason for change: Data Entry Error |                             | 31 Mar 2021 22:59:55 |
| User signature succeeded.                                  | Valentine Ebuh (b) (4)      | 28 Mar 2021 01:06:13 |
| User entered 'No (N)'                                      | (b) (4)<br>(b) (4), (b) (6) | 26 Mar 2021 14:46:59 |

US3092245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:10:08

Procedure/Surgery date (dd MMM yyyy)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| User signature succeeded.  | Valentine Ebuh (b) (4) | 29 Apr 2021 02:23:41 |
|                            | (b) (4)                |                      |
| Signature has been broken. | Vicki Martinez (b) (4) | 24 Apr 2021 00:17:18 |
|                            | (b) (4)                |                      |
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:26:51 |
|                            |                        |                      |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
|                            | (b) (4)                |                      |
| User entered '22 Nov 2020' | (b) (4), (b) (6)       | 31 Mar 2021 23:04:34 |
|                            |                        |                      |

US3092245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:10:08

[Procedure/Surgery](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.   | (b) (4), (b) (6)            | 20 Apr 2021 20:26:53 |
| User signature succeeded.   | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| User entered 'PHYSICAL THERAPY' reason for change: Data Entry Error | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:34:23 |
| User entered 'Physical/Occupational Therapy'                        |                             | 31 Mar 2021 23:04:34 |

**US3092245**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| DataPoint Verified.               | (b) (4), (b) (6)            | 20 Apr 2021 20:26:55 |
| User signature succeeded.         | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| User entered 'Adverse Event (AE)' | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 23:04:34 |

US3092245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:10:08

If indication is Other, specify

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:26:56 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 31 Mar 2021 23:04:34 |

**US3092245**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 15:10:08**

**Procedure/Surgery date (dd MMM yyyy)**

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 05:05:27 |
| DataPoint Verified.        |                             | 20 Apr 2021 20:26:59 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| User entered '22 Nov 2020' | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:35:27 |



US3092245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:10:08

[Procedure/Surgery](#)

| Audit                               | User                        | Time (GMT)           |
|-------------------------------------|-----------------------------|----------------------|
| Data hard locked.                   | (b) (4), (b) (6)            | 01 May 2021 05:05:27 |
| DataPoint Verified.                 |                             | 20 Apr 2021 20:27:01 |
| User signature succeeded.           | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| User entered 'OCCUPATIONAL THERAPY' | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:35:27 |

US3092245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:10:08

[Indication](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| Data hard locked.                 | (b) (4), (b) (6)            | 01 May 2021 05:05:27 |
| DataPoint Verified.               |                             | 20 Apr 2021 20:27:02 |
| User signature succeeded.         | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| User entered 'Adverse Event (AE)' | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:35:27 |

**US3092245**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 09 Jun 2021 15:10:08**

[If indication is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 05:05:27 |
| DataPoint Verified.       |                             | 20 Apr 2021 20:27:04 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 01 Apr 2021 15:35:27 |
|                           |                             |                      |

US3092245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:10:08

Procedure/Surgery date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 05:05:32 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered '03 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:25:51 |

US3092245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:10:08

[Procedure/Surgery](#)

| Audit                              | User                        | Time (GMT)           |
|------------------------------------|-----------------------------|----------------------|
| Data hard locked.                  | (b) (4), (b) (6)            | 01 May 2021 05:05:32 |
| User signature succeeded.          | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered 'URODYNAMICS TESTING' | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:25:51 |

**US3092245**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Indication](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| Data hard locked.                 | (b) (4), (b) (6)            | 01 May 2021 05:05:32 |
| User signature succeeded.         | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered 'Adverse Event (AE)' | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:25:51 |

**US3092245**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 15:10:08**

[If indication is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 05:05:32 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:25:51 |

US3092245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:10:08

Procedure/Surgery date (*dd MMM yyyy*)

| Audit                      | User                        | Time (GMT)           |
|----------------------------|-----------------------------|----------------------|
| Data hard locked.          | (b) (4), (b) (6)            | 01 May 2021 05:05:35 |
| User signature succeeded.  | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered '09 Mar 2021' | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:28:20 |



**US3092245**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Procedure/Surgery](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 05:05:35 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered 'CYTOSCOPY'  | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:28:20 |

US3092245

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:10:08

[Indication](#)

| Audit                             | User                        | Time (GMT)           |
|-----------------------------------|-----------------------------|----------------------|
| Data hard locked.                 | (b) (4), (b) (6)            | 01 May 2021 05:05:35 |
| User signature succeeded.         | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered 'Adverse Event (AE)' | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:28:20 |

**US3092245**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 15:10:08**

[If indication is Other, specify](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| Data hard locked.         | (b) (4), (b) (6)            | 01 May 2021 05:05:35 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| User entered empty.       | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 18:28:20 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded.                             | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered<br>'USA-US086-2020-MRNA-1273-P301000007' | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Serious

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:47 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:49 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |



**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Valentine'  | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Ebuh'       | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Street

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Verified.                           |                        | 04 Mar 2021 22:14:05 |
| User signature succeeded.                     | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Un-reviewed for Safety.                       | (b) (4)                |                      |
| Un-reviewed for Safety.                       | System                 | 21 Dec 2020 16:23:21 |
| User entered '2701 S Hampton Road, Suite 250' | System                 | 21 Dec 2020 16:23:21 |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                       |                        |                      |
| Un-reviewed for Safety.                       | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|   | (b) (4)                |                      |
| User entered '2701 S. Hampton Rd., Suite 250' | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| reason for change: Data Entry Error           | (b) (4)                |                      |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                          | System                 | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: [City](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)                  | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                      | (b) (4)<br>(b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                   | Vicki Martinez (b) (4)            | 07 Dec 2020 20:11:11 |
| User entered 'Dallas' reason for change: Data Entry Error | (b) (4)<br>Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)                  | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                                      | System                            | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'TX'         | System                      | 25 Nov 2020 16:03:25 |



US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Postal Code

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 29 Apr 2021 02:23:41 |
| DataPoint Verified.                                      | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 20 Apr 2021 20:37:49 |
| Un-reviewed for Safety.                                  |                        | 20 Apr 2021 20:31:42 |
| Signature has been broken.                               |                        | 20 Apr 2021 20:31:42 |
| User entered '75224' reason for change: Data Entry Error |                        | 20 Apr 2021 20:31:42 |
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 23 Mar 2021 22:52:09 |
| Reviewed for Safety.                                     | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Un-verified.                                   | System                 | 12 Mar 2021 16:59:30 |
| Signature has been broken.                               | System                 | 12 Mar 2021 16:59:30 |
| User entered (b) (6)                                     | System                 | 12 Mar 2021 16:59:30 |
| DataPoint Verified.                                      | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
|  | (b) (4)                |                      |
| User entered '75244' reason for change: Data Entry Error | Robert Miranda (b) (4) | 28 Dec 2020 22:20:01 |
|  | (b) (4)                |                      |
| Un-reviewed for Safety.                                  | System                 | 21 Dec 2020 16:23:21 |
| User entered (b) (6)                                     | System                 | 21 Dec 2020 16:23:21 |
| (non-conformant).  |                        |                      |
| Reviewed for Safety.                                     | (b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                  | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|  | (b) (4)                |                      |
| User entered '75224' reason for change: Data Entry Error | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|  | (b) (4)                |                      |
| Reviewed for Safety.                                     | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                                     | System                 | 25 Nov 2020 16:03:25 |
| (non-conformant).  |                        |                      |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Dec 2020 16:23:13 |
| User entered 'US'         | System                      | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '7'          | System                 | 12 Apr 2021 18:43:51 |
| User entered '6'          | System                 | 02 Apr 2021 12:56:07 |
| User entered '5'          | System                 | 29 Mar 2021 14:20:33 |
| User entered '4'          | System                 | 12 Mar 2021 19:07:59 |
| User entered '3'          | System                 | 12 Mar 2021 16:59:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                |                      |
| User entered '2'          | System                 | 21 Dec 2020 16:23:21 |
| User entered '1'          | System                 | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded.                             | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered<br>'USA-US086-2020-MRNA-1273-P301000007' | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Serious

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:47 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:49 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |



**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Valentine'  | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Ebuh'       | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Street

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Verified.                           |                        | 04 Mar 2021 22:14:05 |
| User signature succeeded.                     | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Un-reviewed for Safety.                       | (b) (4)                |                      |
| Un-reviewed for Safety.                       | System                 | 21 Dec 2020 16:23:21 |
| User entered '2701 S Hampton Road, Suite 250' | System                 | 21 Dec 2020 16:23:21 |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                       |                        |                      |
| Un-reviewed for Safety.                       | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|   | (b) (4)                |                      |
| User entered '2701 S. Hampton Rd., Suite 250' | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| reason for change: Data Entry Error           | (b) (4)                |                      |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                          | System                 | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: [City](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)                  | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                      | (b) (4)<br>(b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                   | Vicki Martinez (b) (4)            | 07 Dec 2020 20:11:11 |
| User entered 'Dallas' reason for change: Data Entry Error | (b) (4)<br>Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)                  | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                                      | System                            | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'TX'         | System                      | 25 Nov 2020 16:03:25 |



US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Postal Code

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 29 Apr 2021 02:23:41 |
| DataPoint Verified.                                      | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 20 Apr 2021 20:37:49 |
| Un-reviewed for Safety.                                  |                        | 20 Apr 2021 20:31:42 |
| Signature has been broken.                               |                        | 20 Apr 2021 20:31:42 |
| User entered '75224' reason for change: Data Entry Error |                        | 20 Apr 2021 20:31:42 |
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 23 Mar 2021 22:52:09 |
| Reviewed for Safety.                                     | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Un-verified.                                   | System                 | 12 Mar 2021 16:59:30 |
| Signature has been broken.                               | System                 | 12 Mar 2021 16:59:30 |
| User entered (b) (6)                                     | System                 | 12 Mar 2021 16:59:30 |
| DataPoint Verified.                                      | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
|  | (b) (4)                |                      |
| User entered '75244' reason for change: Data Entry Error | Robert Miranda (b) (4) | 28 Dec 2020 22:20:01 |
|  | (b) (4)                |                      |
| Un-reviewed for Safety.                                  | System                 | 21 Dec 2020 16:23:21 |
| User entered (b) (6)                                     | System                 | 21 Dec 2020 16:23:21 |
| (non-conformant).  |                        |                      |
| Reviewed for Safety.                                     | (b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                  | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|  | (b) (4)                |                      |
| User entered '75224' reason for change: Data Entry Error | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|  | (b) (4)                |                      |
| Reviewed for Safety.                                     | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                                     | System                 | 25 Nov 2020 16:03:25 |
| (non-conformant).  |                        |                      |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Dec 2020 16:23:13 |
| User entered 'US'         | System                      | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '7'          | System                 | 12 Apr 2021 18:43:51 |
| User entered '6'          | System                 | 02 Apr 2021 12:56:07 |
| User entered '5'          | System                 | 29 Mar 2021 14:20:33 |
| User entered '4'          | System                 | 12 Mar 2021 19:07:59 |
| User entered '3'          | System                 | 12 Mar 2021 16:59:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                |                      |
| User entered '2'          | System                 | 21 Dec 2020 16:23:21 |
| User entered '1'          | System                 | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.        | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered '25/Nov/2020 11:03' | (b) (4)<br>System      | 25 Nov 2020 16:03:47 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:10:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Dec 2020 16:23:13 |
| User entered 'I'          |                             | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded.                             | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered<br>'USA-US086-2020-MRNA-1273-P301000007' | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Serious

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:47 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |



**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:49 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Valentine'  | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Ebuh'       | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Street

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Verified.                           |                        | 04 Mar 2021 22:14:05 |
| User signature succeeded.                     | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Un-reviewed for Safety.                       | (b) (4)                |                      |
| Un-reviewed for Safety.                       | System                 | 21 Dec 2020 16:23:21 |
| User entered '2701 S Hampton Road, Suite 250' | System                 | 21 Dec 2020 16:23:21 |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                       |                        |                      |
| Un-reviewed for Safety.                       | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|   | (b) (4)                |                      |
| User entered '2701 S. Hampton Rd., Suite 250' | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| reason for change: Data Entry Error           | (b) (4)                |                      |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                          | System                 | 25 Nov 2020 16:03:25 |



US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: [City](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)                  | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                      | (b) (4)<br>(b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                   | Vicki Martinez (b) (4)            | 07 Dec 2020 20:11:11 |
| User entered 'Dallas' reason for change: Data Entry Error | (b) (4)<br>Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)                  | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                                      | System                            | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'TX'         | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Postal Code

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 29 Apr 2021 02:23:41 |
| DataPoint Verified.                                      | (b) (4)                | 20 Apr 2021 20:37:49 |
| Un-reviewed for Safety.                                  | (b) (4), (b) (6)       |                      |
| Signature has been broken.                               |                        |                      |
| User entered '75224' reason for change: Data Entry Error |                        |                      |
| User signature succeeded.                                | Valentine Ebuh (b) (4) |                      |
| Reviewed for Safety.                                     | (b) (4)                | 12 Mar 2021 19:07:48 |
| DataPoint Un-verified.                                   | (b) (4), (b) (6)       |                      |
| Signature has been broken.                               |                        | 12 Mar 2021 16:59:30 |
| User entered (b) (6)                                     | System                 |                      |
| DataPoint Verified.                                      | System                 |                      |
|  | System                 | 12 Mar 2021 16:59:30 |
|  | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered '75244' reason for change: Data Entry Error | (b) (4)                | 28 Dec 2020 22:20:01 |
| Un-reviewed for Safety.                                  | Robert Miranda (b) (4) |                      |
| User entered (b) (6)                                     | (b) (4)                | 21 Dec 2020 16:23:21 |
| (non-conformant).  | System                 |                      |
| Reviewed for Safety.                                     | System                 | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                  | (b) (4), (b) (6)       |                      |
|  |                        | 07 Dec 2020 20:11:11 |
| User entered '75224' reason for change: Data Entry Error | Vicki Martinez (b) (4) |                      |
| Reviewed for Safety.                                     | (b) (4)                | 07 Dec 2020 20:11:11 |
|  | (b) (4), (b) (6)       |                      |
| User entered (b) (6)                                     | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| (non-conformant).  |                        | 25 Nov 2020 16:03:25 |
|  | System                 |                      |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Dec 2020 16:23:13 |
| User entered 'US'         | System                      | 25 Nov 2020 16:03:47 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '7'          | System                 | 12 Apr 2021 18:43:51 |
| User entered '6'          | System                 | 02 Apr 2021 12:56:07 |
| User entered '5'          | System                 | 29 Mar 2021 14:20:33 |
| User entered '4'          | System                 | 12 Mar 2021 19:07:59 |
| User entered '3'          | System                 | 12 Mar 2021 16:59:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                |                      |
| User entered '2'          | System                 | 21 Dec 2020 16:23:21 |
| User entered '1'          | System                 | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:10:08**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.        | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| User entered '21/Dec/2020 16:23' | (b) (4)<br>System      | 21 Dec 2020 16:23:21 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:10:08

**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)            | 12 Mar 2021 19:07:48 |
| DataPoint Verified.       |                             | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 21 Dec 2020 16:23:21 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded.                             | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered<br>'USA-US086-2020-MRNA-1273-P301000007' | System                      | 25 Nov 2020 16:03:25 |



US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Serious

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:47 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:49 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4)                |                      |
|                            | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Valentine'  | System                      | 25 Nov 2020 16:03:25 |



**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Ebuh'       | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Street

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Verified.                           |                        | 04 Mar 2021 22:14:05 |
| User signature succeeded.                     | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Un-reviewed for Safety.                       | (b) (4)                |                      |
| Un-reviewed for Safety.                       | System                 | 21 Dec 2020 16:23:21 |
| User entered '2701 S Hampton Road, Suite 250' | System                 | 21 Dec 2020 16:23:21 |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                       |                        |                      |
| Un-reviewed for Safety.                       | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|   | (b) (4)                |                      |
| User entered '2701 S. Hampton Rd., Suite 250' | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| reason for change: Data Entry Error           | (b) (4)                |                      |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                          |                        |                      |
|   | System                 | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: [City](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)                  | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                      | (b) (4)<br>(b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                   | Vicki Martinez (b) (4)            | 07 Dec 2020 20:11:11 |
| User entered 'Dallas' reason for change: Data Entry Error | (b) (4)<br>Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)                  | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                                      | System                            | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'TX'         | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Postal Code

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                | Valentine Ebuh (b) (4)            | 29 Apr 2021 02:23:41 |
| DataPoint Verified.                                      | (b) (4)<br>(b) (4), (b) (6)       | 20 Apr 2021 20:37:49 |
| Un-reviewed for Safety.                                  |                                   | 20 Apr 2021 20:31:42 |
| Signature has been broken.                               |                                   | 20 Apr 2021 20:31:42 |
| User entered '75224' reason for change: Data Entry Error |                                   | 20 Apr 2021 20:31:42 |
| User signature succeeded.                                | Valentine Ebuh (b) (4)            | 23 Mar 2021 22:52:09 |
| Reviewed for Safety.                                     | (b) (4)<br>(b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Un-verified.                                   | System                            | 12 Mar 2021 16:59:30 |
| Signature has been broken.                               | System                            | 12 Mar 2021 16:59:30 |
| User entered (b) (6)                                     | System                            | 12 Mar 2021 16:59:30 |
| DataPoint Verified.                                      | (b) (4), (b) (6)                  | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '75244' reason for change: Data Entry Error | (b) (4)<br>Robert Miranda (b) (4) | 28 Dec 2020 22:20:01 |
| Un-reviewed for Safety.                                  | (b) (4)<br>System                 | 21 Dec 2020 16:23:21 |
| User entered (b) (6)<br>(non-conformant).                | System                            | 21 Dec 2020 16:23:21 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)                  | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                  | Vicki Martinez (b) (4)<br>(b) (4) | 07 Dec 2020 20:11:11 |
| User entered '75224' reason for change: Data Entry Error | Vicki Martinez (b) (4)<br>(b) (4) | 07 Dec 2020 20:11:11 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)                  | 25 Nov 2020 16:03:40 |
| User entered (b) (6)<br>(non-conformant).                | System                            | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Dec 2020 16:23:13 |
| User entered 'US'         | System                      | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '7'          | System                 | 12 Apr 2021 18:43:51 |
| User entered '6'          | System                 | 02 Apr 2021 12:56:07 |
| User entered '5'          | System                 | 29 Mar 2021 14:20:33 |
| User entered '4'          | System                 | 12 Mar 2021 19:07:59 |
| User entered '3'          | System                 | 12 Mar 2021 16:59:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                |                      |
| User entered '2'          | System                 | 21 Dec 2020 16:23:21 |
| User entered '1'          | System                 | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:10:08**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 20 Apr 2021 20:38:12 |
| User signature succeeded.        | Valentine Ebuh (b) (4) | 23 Mar 2021 22:52:09 |
| User entered '12/Mar/2021 11:59' | (b) (4)<br>System      | 12 Mar 2021 16:59:30 |



US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:10:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:38:12 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 19:07:48 |
| User entered 'I'          |                             | 12 Mar 2021 16:59:30 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded.                             | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered<br>'USA-US086-2020-MRNA-1273-P301000007' | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Serious

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:47 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:49 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |



**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Valentine'  | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Ebuh'       | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Street

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Verified.                           |                        | 04 Mar 2021 22:14:05 |
| User signature succeeded.                     | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Un-reviewed for Safety.                       | (b) (4)                |                      |
| Un-reviewed for Safety.                       | System                 | 21 Dec 2020 16:23:21 |
| User entered '2701 S Hampton Road, Suite 250' | System                 | 21 Dec 2020 16:23:21 |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                       |                        |                      |
| Un-reviewed for Safety.                       | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|   | (b) (4)                |                      |
| User entered '2701 S. Hampton Rd., Suite 250' | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| reason for change: Data Entry Error           | (b) (4)                |                      |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                          |                        |                      |
|   | System                 | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: [City](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)                  | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                      | (b) (4)<br>(b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                   | Vicki Martinez (b) (4)            | 07 Dec 2020 20:11:11 |
| User entered 'Dallas' reason for change: Data Entry Error | (b) (4)<br>Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)                  | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                                      | System                            | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'TX'         | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Postal Code

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 29 Apr 2021 02:23:41 |
| DataPoint Verified.                                      | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 20 Apr 2021 20:37:49 |
| Un-reviewed for Safety.                                  |                        | 20 Apr 2021 20:31:42 |
| Signature has been broken.                               |                        | 20 Apr 2021 20:31:42 |
| User entered '75224' reason for change: Data Entry Error |                        | 20 Apr 2021 20:31:42 |
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 23 Mar 2021 22:52:09 |
| Reviewed for Safety.                                     | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Un-verified.                                   | System                 | 12 Mar 2021 16:59:30 |
| Signature has been broken.                               | System                 | 12 Mar 2021 16:59:30 |
| User entered (b) (6)                                     | System                 | 12 Mar 2021 16:59:30 |
| DataPoint Verified.                                      | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
|  | (b) (4)                |                      |
| User entered '75244' reason for change: Data Entry Error | Robert Miranda (b) (4) | 28 Dec 2020 22:20:01 |
|  | (b) (4)                |                      |
| Un-reviewed for Safety.                                  | System                 | 21 Dec 2020 16:23:21 |
| User entered (b) (6)                                     | System                 | 21 Dec 2020 16:23:21 |
| (non-conformant).  |                        |                      |
| Reviewed for Safety.                                     | (b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                  | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|  | (b) (4)                |                      |
| User entered '75224' reason for change: Data Entry Error | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|  | (b) (4)                |                      |
| Reviewed for Safety.                                     | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                                     | System                 | 25 Nov 2020 16:03:25 |
| (non-conformant).  |                        |                      |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Dec 2020 16:23:13 |
| User entered 'US'         | System                      | 25 Nov 2020 16:03:47 |



**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '7'          | System                 | 12 Apr 2021 18:43:51 |
| User entered '6'          | System                 | 02 Apr 2021 12:56:07 |
| User entered '5'          | System                 | 29 Mar 2021 14:20:33 |
| User entered '4'          | System                 | 12 Mar 2021 19:07:59 |
| User entered '3'          | System                 | 12 Mar 2021 16:59:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                |                      |
| User entered '2'          | System                 | 21 Dec 2020 16:23:21 |
| User entered '1'          | System                 | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 15:10:08**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 20 Apr 2021 20:38:12 |
| User signature succeeded.        | Valentine Ebuh (b) (4) | 23 Mar 2021 22:52:09 |
| User entered '12/Mar/2021 19:07' | (b) (4)<br>System      | 12 Mar 2021 19:07:59 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:10:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:38:12 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Mar 2021 22:52:09 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 12 Mar 2021 19:07:59 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded.                             | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered<br>'USA-US086-2020-MRNA-1273-P301000007' | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Serious

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:47 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:49 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |



**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Valentine'  | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Ebuh'       | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Street

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Verified.                           |                        | 04 Mar 2021 22:14:05 |
| User signature succeeded.                     | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Un-reviewed for Safety.                       | (b) (4)                |                      |
| Un-reviewed for Safety.                       | System                 | 21 Dec 2020 16:23:21 |
| User entered '2701 S Hampton Road, Suite 250' | System                 | 21 Dec 2020 16:23:21 |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                       |                        |                      |
| Un-reviewed for Safety.                       | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|   | (b) (4)                |                      |
| User entered '2701 S. Hampton Rd., Suite 250' | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| reason for change: Data Entry Error           | (b) (4)                |                      |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                          | System                 | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: [City](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)                  | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                      | (b) (4)<br>(b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                   | Vicki Martinez (b) (4)            | 07 Dec 2020 20:11:11 |
| User entered 'Dallas' reason for change: Data Entry Error | (b) (4)<br>Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)                  | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                                      | System                            | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'TX'         | System                      | 25 Nov 2020 16:03:25 |



US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Postal Code

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 29 Apr 2021 02:23:41 |
| DataPoint Verified.                                      | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 20 Apr 2021 20:37:49 |
| Un-reviewed for Safety.                                  |                        | 20 Apr 2021 20:31:42 |
| Signature has been broken.                               |                        | 20 Apr 2021 20:31:42 |
| User entered '75224' reason for change: Data Entry Error |                        | 20 Apr 2021 20:31:42 |
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 23 Mar 2021 22:52:09 |
| Reviewed for Safety.                                     | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Un-verified.                                   | System                 | 12 Mar 2021 16:59:30 |
| Signature has been broken.                               | System                 | 12 Mar 2021 16:59:30 |
| User entered (b) (6)                                     | System                 | 12 Mar 2021 16:59:30 |
| DataPoint Verified.                                      | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
|  | (b) (4)                |                      |
| User entered '75244' reason for change: Data Entry Error | Robert Miranda (b) (4) | 28 Dec 2020 22:20:01 |
|  | (b) (4)                |                      |
| Un-reviewed for Safety.                                  | System                 | 21 Dec 2020 16:23:21 |
| User entered (b) (6)                                     | System                 | 21 Dec 2020 16:23:21 |
| (non-conformant).  |                        |                      |
| Reviewed for Safety.                                     | (b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                  | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|  | (b) (4)                |                      |
| User entered '75224' reason for change: Data Entry Error | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|  | (b) (4)                |                      |
| Reviewed for Safety.                                     | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                                     | System                 | 25 Nov 2020 16:03:25 |
| (non-conformant).  |                        |                      |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Dec 2020 16:23:13 |
| User entered 'US'         | System                      | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '7'          | System                 | 12 Apr 2021 18:43:51 |
| User entered '6'          | System                 | 02 Apr 2021 12:56:07 |
| User entered '5'          | System                 | 29 Mar 2021 14:20:33 |
| User entered '4'          | System                 | 12 Mar 2021 19:07:59 |
| User entered '3'          | System                 | 12 Mar 2021 16:59:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                |                      |
| User entered '2'          | System                 | 21 Dec 2020 16:23:21 |
| User entered '1'          | System                 | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 15:10:08**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 20 Apr 2021 20:38:12 |
| User signature succeeded.        | Valentine Ebuh (b) (4) | 31 Mar 2021 16:41:20 |
| User entered '29/Mar/2021 10:20' | (b) (4)<br>System      | 29 Mar 2021 14:20:33 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:10:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:38:12 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 31 Mar 2021 16:41:20 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 29 Mar 2021 14:20:33 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded.                             | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered<br>'USA-US086-2020-MRNA-1273-P301000007' | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Serious

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:47 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |



**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:49 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Valentine'  | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Ebuh'       | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Street

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Verified.                           |                        | 04 Mar 2021 22:14:05 |
| User signature succeeded.                     | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Un-reviewed for Safety.                       | (b) (4)                |                      |
| Un-reviewed for Safety.                       | System                 | 21 Dec 2020 16:23:21 |
| User entered '2701 S Hampton Road, Suite 250' | System                 | 21 Dec 2020 16:23:21 |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                       |                        |                      |
| Un-reviewed for Safety.                       | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|   | (b) (4)                |                      |
| User entered '2701 S. Hampton Rd., Suite 250' | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| reason for change: Data Entry Error           | (b) (4)                |                      |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                          |                        |                      |
|   | System                 | 25 Nov 2020 16:03:25 |



US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: [City](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)                  | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                      | (b) (4)<br>(b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                   | Vicki Martinez (b) (4)            | 07 Dec 2020 20:11:11 |
| User entered 'Dallas' reason for change: Data Entry Error | (b) (4)<br>Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)                  | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                                      | System                            | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'TX'         | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Postal Code

| Audit  | User                   | Time (GMT)           |
|--|------------------------|----------------------|
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 29 Apr 2021 02:23:41 |
| DataPoint Verified.                                      | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 20 Apr 2021 20:37:49 |
| Un-reviewed for Safety.                                  |                        | 20 Apr 2021 20:31:42 |
| Signature has been broken.                               |                        | 20 Apr 2021 20:31:42 |
| User entered '75224' reason for change: Data Entry Error |                        | 20 Apr 2021 20:31:42 |
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 23 Mar 2021 22:52:09 |
| Reviewed for Safety.                                     | (b) (4)                |                      |
|  | (b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Un-verified.                                   | System                 | 12 Mar 2021 16:59:30 |
| Signature has been broken.                               | System                 | 12 Mar 2021 16:59:30 |
| User entered (b) (6)                                     | System                 | 12 Mar 2021 16:59:30 |
| DataPoint Verified.                                      | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
|  | (b) (4)                |                      |
| User entered '75244' reason for change: Data Entry Error | Robert Miranda (b) (4) | 28 Dec 2020 22:20:01 |
|  | (b) (4)                |                      |
| Un-reviewed for Safety.                                  | System                 | 21 Dec 2020 16:23:21 |
| User entered (b) (6)                                     | System                 | 21 Dec 2020 16:23:21 |
| (non-conformant).  |                        |                      |
| Reviewed for Safety.                                     | (b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                  | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|  | (b) (4)                |                      |
| User entered '75224' reason for change: Data Entry Error | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|  | (b) (4)                |                      |
| Reviewed for Safety.                                     | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                                     | System                 | 25 Nov 2020 16:03:25 |
| (non-conformant).  |                        |                      |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Dec 2020 16:23:13 |
| User entered 'US'         | System                      | 25 Nov 2020 16:03:47 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '7'          | System                 | 12 Apr 2021 18:43:51 |
| User entered '6'          | System                 | 02 Apr 2021 12:56:07 |
| User entered '5'          | System                 | 29 Mar 2021 14:20:33 |
| User entered '4'          | System                 | 12 Mar 2021 19:07:59 |
| User entered '3'          | System                 | 12 Mar 2021 16:59:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                |                      |
| User entered '2'          | System                 | 21 Dec 2020 16:23:21 |
| User entered '1'          | System                 | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 15:10:08**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 20 Apr 2021 20:38:12 |
| User signature succeeded.        | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered '02/Apr/2021 05:56' | (b) (4)<br>System      | 02 Apr 2021 12:56:07 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:10:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:38:12 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 12:56:07 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded.                             | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered<br>'USA-US086-2020-MRNA-1273-P301000007' | System                      | 25 Nov 2020 16:03:25 |



US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Serious

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:47 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                      | User                   | Time (GMT)           |
|----------------------------|------------------------|----------------------|
| DataPoint Verified.        | (b) (4), (b) (6)       | 20 Apr 2021 20:29:49 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered 'Yes (Y)'     | System                 | 02 Apr 2021 12:55:42 |
| Un-reviewed for Safety.    | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Un-verified.     | System                 | 31 Mar 2021 22:51:12 |
| Signature has been broken. | System                 | 31 Mar 2021 22:51:12 |
| User entered 'No (N)'      | System                 | 31 Mar 2021 22:51:12 |
| DataPoint Verified.        | (b) (4), (b) (6)       | 04 Mar 2021 22:14:05 |
| User signature succeeded.  | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.       | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered 'Yes (Y)'     | System                 | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'No (N)'     | System                      | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Valentine'  | System                      | 25 Nov 2020 16:03:25 |



**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'Ebuh'       | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Street

| Audit   | User                   | Time (GMT)           |
|---|------------------------|----------------------|
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Verified.                           |                        | 04 Mar 2021 22:14:05 |
| User signature succeeded.                     | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
| Un-reviewed for Safety.                       | (b) (4)                |                      |
| Un-reviewed for Safety.                       | System                 | 21 Dec 2020 16:23:21 |
| User entered '2701 S Hampton Road, Suite 250' | System                 | 21 Dec 2020 16:23:21 |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                       |                        |                      |
| Un-reviewed for Safety.                       | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
|   | (b) (4)                |                      |
| User entered '2701 S. Hampton Rd., Suite 250' | Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| reason for change: Data Entry Error           | (b) (4)                |                      |
| Reviewed for Safety.                          | (b) (4), (b) (6)       | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                          | System                 | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: [City](#)

| Audit   | User                              | Time (GMT)           |
|---|-----------------------------------|----------------------|
| DataPoint Verified.                                       | (b) (4), (b) (6)                  | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                 | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.                                      | (b) (4)<br>(b) (4), (b) (6)       | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                   | Vicki Martinez (b) (4)            | 07 Dec 2020 20:11:11 |
| User entered 'Dallas' reason for change: Data Entry Error | (b) (4)<br>Vicki Martinez (b) (4) | 07 Dec 2020 20:11:11 |
| Reviewed for Safety.                                      | (b) (4), (b) (6)                  | 25 Nov 2020 16:03:40 |
| User entered (b) (6)                                      | System                            | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 25 Nov 2020 16:03:40 |
| User entered 'TX'         | System                      | 25 Nov 2020 16:03:25 |

US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Postal Code

| Audit  | User                              | Time (GMT)           |
|--|-----------------------------------|----------------------|
| User signature succeeded.                                | Valentine Ebuh (b) (4)            | 29 Apr 2021 02:23:41 |
| DataPoint Verified.                                      | (b) (4)<br>(b) (4), (b) (6)       | 20 Apr 2021 20:37:49 |
| Un-reviewed for Safety.                                  |                                   | 20 Apr 2021 20:31:42 |
| Signature has been broken.                               |                                   | 20 Apr 2021 20:31:42 |
| User entered '75224' reason for change: Data Entry Error |                                   | 20 Apr 2021 20:31:42 |
| User signature succeeded.                                | Valentine Ebuh (b) (4)            | 23 Mar 2021 22:52:09 |
| Reviewed for Safety.                                     | (b) (4)<br>(b) (4), (b) (6)       | 12 Mar 2021 19:07:48 |
| DataPoint Un-verified.                                   | System                            | 12 Mar 2021 16:59:30 |
| Signature has been broken.                               | System                            | 12 Mar 2021 16:59:30 |
| User entered (b) (6)                                     | System                            | 12 Mar 2021 16:59:30 |
| DataPoint Verified.                                      | (b) (4), (b) (6)                  | 04 Mar 2021 22:14:05 |
| User signature succeeded.                                | Valentine Ebuh (b) (4)            | 23 Feb 2021 03:47:23 |
| User entered '75244' reason for change: Data Entry Error | (b) (4)<br>Robert Miranda (b) (4) | 28 Dec 2020 22:20:01 |
| Un-reviewed for Safety.                                  | (b) (4)<br>System                 | 21 Dec 2020 16:23:21 |
| User entered (b) (6)<br>(non-conformant).                | System                            | 21 Dec 2020 16:23:21 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)                  | 21 Dec 2020 16:23:13 |
| Un-reviewed for Safety.                                  | Vicki Martinez (b) (4)<br>(b) (4) | 07 Dec 2020 20:11:11 |
| User entered '75224' reason for change: Data Entry Error | Vicki Martinez (b) (4)<br>(b) (4) | 07 Dec 2020 20:11:11 |
| Reviewed for Safety.                                     | (b) (4), (b) (6)                  | 25 Nov 2020 16:03:40 |
| User entered (b) (6)<br>(non-conformant).                | System                            | 25 Nov 2020 16:03:25 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 04 Mar 2021 22:14:05 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 23 Feb 2021 03:47:23 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 21 Dec 2020 16:23:13 |
| User entered 'US'         | System                      | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit                     | User                   | Time (GMT)           |
|---------------------------|------------------------|----------------------|
| User entered '7'          | System                 | 12 Apr 2021 18:43:51 |
| User entered '6'          | System                 | 02 Apr 2021 12:56:07 |
| User entered '5'          | System                 | 29 Mar 2021 14:20:33 |
| User entered '4'          | System                 | 12 Mar 2021 19:07:59 |
| User entered '3'          | System                 | 12 Mar 2021 16:59:30 |
| User signature succeeded. | Valentine Ebuh (b) (4) | 23 Feb 2021 03:47:23 |
|                           | (b) (4)                |                      |
| User entered '2'          | System                 | 21 Dec 2020 16:23:21 |
| User entered '1'          | System                 | 25 Nov 2020 16:03:47 |

**US3092245**

**Folder: SAE USA-US086-2020-MRNA-1273-P301000007**

**Form: Safety Report Form (7)**

**Generated On: 09 Jun 2021 15:10:08**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 20 Apr 2021 20:38:12 |
| User signature succeeded.        | Valentine Ebuh (b) (4) | 14 Apr 2021 01:03:51 |
| User entered '12/Apr/2021 11:43' | (b) (4)<br>System      | 12 Apr 2021 18:43:51 |



US3092245

Folder: SAE USA-US086-2020-MRNA-1273-P301000007

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:10:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:38:12 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 14 Apr 2021 01:03:51 |
| User entered 'I'          | (b) (4)<br>(b) (4), (b) (6) | 12 Apr 2021 18:43:51 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded.                             | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered<br>'USA-US086-2021-MRNA-1273-P301000014' | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'Yes (Y)'    | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'No (N)'     | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'No (N)'     | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'Yes (Y)'    | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'No (N)'     | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'No (N)'     | System                      | 02 Apr 2021 19:03:59 |



**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'No (N)'     | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'Valentine'  | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'Ebuh'       | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: Street](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                           | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded.                     | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.                          | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered '2701 S Hampton Road, Suite 250' | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'Dallas'     | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'TX'         | System                      | 02 Apr 2021 19:03:59 |

US3092245

Folder: SAE USA-US086-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Postal Code

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| DataPoint Verified.                                      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 20:38:00 |
| Un-reviewed for Safety.                                  |                             | 20 Apr 2021 20:31:53 |
| Signature has been broken.                               |                             | 20 Apr 2021 20:31:53 |
| User entered '75224' reason for change: Data Entry Error |                             | 20 Apr 2021 20:31:53 |
| DataPoint Un-verified.                                   |                             | 20 Apr 2021 20:30:25 |
| DataPoint Verified.                                      |                             | 20 Apr 2021 20:21:34 |
| User signature succeeded.                                | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.                                     | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered (b) (6)                                     | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'US'         | System                      | 02 Apr 2021 19:05:32 |



**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 02 Apr 2021 19:05:32 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[SAEID](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                                   | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded.                             | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.                                  | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered<br>'USA-US086-2021-MRNA-1273-P301000014' | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

**Serious**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'Yes (Y)'    | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Death](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'No (N)'     | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Life threatening](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'No (N)'     | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'Yes (Y)'    | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Persistent or significant disability or incapacity](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'No (N)'     | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Congenital anomaly or birth defect](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'No (N)'     | System                      | 02 Apr 2021 19:03:59 |



**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Other medically important event](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'No (N)'     | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's First Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'Valentine'  | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator's Last Name](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'Ebuh'       | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: Street](#)

| Audit   | User                        | Time (GMT)           |
|---|-----------------------------|----------------------|
| DataPoint Verified.                           | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded.                     | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.                          | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered '2701 S Hampton Road, Suite 250' | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: City](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'Dallas'     | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Site Address: State](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'TX'         | System                      | 02 Apr 2021 19:03:59 |

US3092245

Folder: SAE USA-US086-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 15:10:08

Site Address: Postal Code

| Audit  | User                        | Time (GMT)           |
|--|-----------------------------|----------------------|
| User signature succeeded.                                | Valentine Ebuh (b) (4)      | 29 Apr 2021 02:23:41 |
| DataPoint Verified.                                      | (b) (4)<br>(b) (4), (b) (6) | 20 Apr 2021 20:38:00 |
| Un-reviewed for Safety.                                  |                             | 20 Apr 2021 20:31:53 |
| Signature has been broken.                               |                             | 20 Apr 2021 20:31:53 |
| User entered '75224' reason for change: Data Entry Error |                             | 20 Apr 2021 20:31:53 |
| DataPoint Un-verified.                                   |                             | 20 Apr 2021 20:30:25 |
| DataPoint Verified.                                      |                             | 20 Apr 2021 20:21:34 |
| User signature succeeded.                                | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.                                     | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered (b) (6)                                     | System                      | 02 Apr 2021 19:03:59 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[Investigator Country](#)

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'US'         | System                      | 02 Apr 2021 19:05:32 |



**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:10:08**

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit            | User   | Time (GMT)           |
|------------------|--------|----------------------|
| User entered 'I' | System | 02 Apr 2021 19:05:32 |

**US3092245**

**Folder: SAE USA-US086-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:10:08**

[Date of submission \(Pre-filled from custom function\)](#)

| Audit                            | User                   | Time (GMT)           |
|----------------------------------|------------------------|----------------------|
| DataPoint Verified.              | (b) (4), (b) (6)       | 20 Apr 2021 20:21:34 |
| User signature succeeded.        | Valentine Ebuh (b) (4) | 05 Apr 2021 02:38:58 |
| User entered '02/Apr/2021 12:05' | (b) (4)<br>System      | 02 Apr 2021 19:05:32 |

US3092245

Folder: SAE USA-US086-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:10:08

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

| Audit                     | User                        | Time (GMT)           |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified.       | (b) (4), (b) (6)            | 20 Apr 2021 20:21:34 |
| User signature succeeded. | Valentine Ebuh (b) (4)      | 05 Apr 2021 02:38:58 |
| Reviewed for Safety.      | (b) (4)<br>(b) (4), (b) (6) | 02 Apr 2021 19:05:42 |
| User entered 'I'          |                             | 02 Apr 2021 19:05:32 |